THESIS

FOR THE AWARD OF DEGREE OF

MASTER OF SURGERY (GENERAL SURGERY)

SESSION 2022-2025

"LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT DRAINAGE: A HOSPITAL BASED OBSERVATIONAL STUDY"

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ACKNOWLEDGEMENT

The completion of this project marks a significant milestone in my academic journey, and it would not have been possible without the support and guidance of numerous individuals.

First and foremost, I extend my heartfelt gratitude to Dr. Yogendra Kumar, my esteemed guide, whose unwavering support, profound expertise, and invaluable mentorship have been instrumental in shaping this work. His insightful feedback, encouragement, and patience have been a constant source of inspiration throughout this endeavour. I am profoundly grateful for the opportunity to learn under his guidance.

Furthermore, I extend my sincere thanks to Dr. Amit Kumar, my co-guide, for his invaluable advice, encouragement, and support throughout this project. His expertise and insights have been immensely beneficial.

I would also like to express my gratitude to Dr. Hari Mohan, my co-guide, for his valuable insights, guidance, and assistance throughout this project. His expertise and willingness to share knowledge have greatly contributed to the success of this endeavour.

A special thanks goes out to all my seniors, colleagues, and juniors who have supported me throughout this journey. In particular, I want to express my gratitude to Dr. Soha Yalavarthi, and Dr. Srishti Gupta for their encouragement, camaraderie, and valuable inputs.

I am deeply grateful to my family for their unwavering love, encouragement, and understanding throughout this journey. To my late-father, Dr. Rahul Parasnath Mishra, whose unwavering support and sacrifices have been my guiding light. To my mother, Shipra Mishra and brother, Raunak Mishra, your encouragement and belief in my abilities have always spurred me on.

As I move forward, I aspire to become a skilled surgeon with a deep understanding of my field, a commitment to continuous learning, and a dedication to providing excellent patient care. I humbly seek God's guidance and assistance as I embark on this noble endeavour.

Lastly, I extend my heartfelt gratitude to all my friends and well-wishers who have stood by me with their encouragement and support.

Thank you all for being an integral part of my journey.

DR. GARIMA RAHUL MISHRA

INTRODUCTION

Gallstone disease is a common gastrointestinal disorder that frequently requires hospitalization, with prevalence rates ranging between 11% and 36%.[1] Cholelithiasis represents a significant global health concern, and cholecystectomy remains the treatment of choice. While it affects around 10-15% of people in Western countries, more than 80% of cases are asymptomatic[2]. In India, the prevalence is about 4%. However, approximately 1-2% of these individuals experience symptoms that necessitate surgical treatment annually, making cholecystectomy one of the most commonly performed surgeries[1].

The first cholecystectomy was carried out by Carl Langebuch in 1882, in Germany, followed by the introduction of laparoscopic cholecystectomy by Erich Mühe in 1985[3]. The first laparoscopic cholecystectomy in India was performed in 1990 at JJ Hospital in Mumbai. In 1992, the National Institute of Health (NIH) consensus conference endorsed laparoscopic cholecystectomy as equivalent to open surgery, and it is now regarded as the gold standard for treating symptomatic cholelithiasis.[4] Laparoscopic cholecystectomy offers several advantages over traditional open surgery, such as smaller incisions, less postoperative pain, quicker recovery times, shorter hospital stays, enhanced cosmetic results, and a lower risk of incisional hernias. Consequently, unless contraindicated, laparoscopic cholecystectomy should be the preferred approach in most cases.[5]

Laparoscopic cholecystectomy is generally a safe procedure, with major complications occurring in less than 5% of cases.[6] The broad acceptance of this procedure highlights its efficacy and reliability, making it one of the most frequently performed laparoscopic surgeries globally. It is the second most common gastrointestinal operation, after appendectomy. The shift toward minimally invasive surgery reflects ongoing improvements in surgical practices, which have significantly enhanced patient outcomes.[2,7]

Like any surgical procedure, laparoscopic cholecystectomy is not without its risks, which may range from mild to severe complications, with rare cases being life-threatening. Postoperative symptoms, such as shoulder tip pain, back pain, and nausea, are more common in laparoscopic cholecystectomy compared to open surgery. [4] These symptoms are often linked to carbon dioxide insufflation during the procedure and the manipulation of instruments within the abdominal cavity. To reduce complications and ease postoperative discomfort, surgeons historically employed routine drainage after laparoscopic cholecystectomy.[8] This was intended to address potential issues such as bile

accumulation, bleeding, or fluid buildup, which might require further surgical intervention. Drainage was also thought to help expel carbon dioxide, thereby minimizing post-surgical shoulder pain.

The use of drains after laparoscopic cholecystectomy has been debated due to potential drawbacks. Research has shown that drain placement may increase the risk of infection and prolonged hospital stays. Additionally, patients with drains often report higher rates of nausea and vomiting. This ongoing debate underscores the need for careful decision-making in surgical practice. Although drains may be helpful for managing symptoms and draining fluids, their routine use should be reconsidered in light of the risk of infection and delayed recovery. Surgeons should evaluate each case individually, considering patient characteristics, surgical technique, and any existing risk factors.

Drains have traditionally been used to detect bile leaks, control bleeding, and manage abdominal fluid collections following laparoscopic cholecystectomy. However, as surgical techniques have improved and postoperative care has advanced, the need for drains has diminished. Biliary complications after laparoscopic cholecystectomy are rare, typically occurring in just 0.1% to 0.9% of cases, and hemorrhagic complications are even less common.[10] Consequently, the routine use of drains has decreased. Studies show that the absence of subhepatic fluid collections is associated with smoother recoveries, further reducing the necessity for drains.[14] Additionally, research has shown that drains inserted into fluid-free areas are often quickly covered by omentum, leading to blockages within 48 hours, thereby hindering their ability to drain bile effectively. While surgical site infections remain a concern, affecting 1.1% to 7.9% of patients, they can be mitigated with careful postoperative care, especially in minimally invasive procedures like laparoscopic cholecystectomy.[12,13,15]

In conclusion, the decision to use drains in laparoscopic cholecystectomy should be made with careful consideration of the potential benefits and risks. Although drains may be beneficial in certain situations, their routine use is less common due to the low occurrence of postoperative complications and the limitations of bile drainage. Decisions regarding the use of drains should be based on the individual patient's needs and the surgeon's judgment.

This study aims to compare the outcomes, including length of hospital stay and postoperative complications, between patients with symptomatic cholelithiasis undergoing elective laparoscopic cholecystectomy with and without subhepatic drain placement.

AIM
AND
OBJECTIVES

AIM:

To compare the efficacy in terms of length of hospital stay and postoperative complications in patients with symptomatic cholelithiasis undergoing elective laparoscopic cholecystectomy, with and without subhepatic drainage tube insertion.

OBJECTIVES:

To compare the following in patients undergoing laparoscopic cholecystectomy with and without drainage;

1. The length of hospital stay and

2. Assessment of following complications postoperatively;

- Abdominal pain as per Visual Analogue Scale (On day 0, day 1, day 2 and day 3),
- Shoulder pain as per Visual Analogue Scale (On day 0, day 1, day 2 and day 3),
- Surgical site infection (SSI),
- Fever,
- Nausea,
- Vomiting,
- Haemorrhage.

REVIEW OF LITERATURE

Historical Review

Alexander of Tralles, a physician from the Byzantine Empire, is credited as being the first person to present an explanation of stones in human livers (525-605).[16] In 1937, Gordon Taylor was the first person to present a scientific explanation for gallstone disease, which had been described for the first time in the fourth century BC. The image of human gallstones that Vesalius offered was extremely accurate, and he ultimately concluded that these stones were suggestive of a diseased state.[17]

Laparoscopic cholecystectomy

Philippe Mouret conducted the inaugural laparoscopic cholecystectomy in 1987.[18] The United States of America witnessed the first laparoscopic cholecystectomy done by Mc Kernan and Saye in the year 1988.[19] In 1985, Erich Muhe, a German professor from Boblingen, conducted the inaugural laparoscopic cholecystectomy.[20]

Anatomy

Located in a fossa that is situated amid the right and quadrate lobes of the liver, the gallbladder is a sac that has the shape of a pear and is found on the right lobe of the liver. The gallbladder is composed of three primary aspects: A spherical end termed the fundus, that may project from the bottom edge of the liver, a wider piece described as the body, which can be found adjacent to the transverse colon with the top part of the duodenum and a thin section called the neck, which includes mucous folds that form a spiral fold.

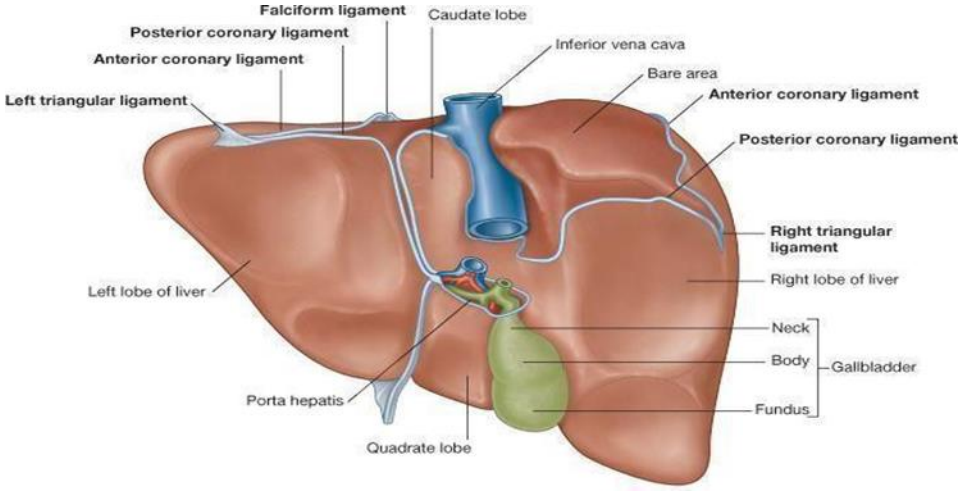


Figure 1: Gallbladder anatomy

The gallbladder has a length of around 7 to 10 cm and a breadth of 2.5 to 3.5 cm. The bile has a volume ranging from 50 to 60 millilitres. Hartmann's pouch is a protrusion of the infundibulum located in close juxtaposition to the neck of the gallbladder. This is where gallstones typically become trapped. The neck connects with the cystic duct [23]

The gallbladder consists of five layers: The innermost layer – epithelium, lamina propria, the smooth muscle, the peri muscular subserosal connective tissue, and the serosa. The gallbladder lacks muscularis mucosa or submucosa.[24]

Both the right as well as left hepatic ducts meet beyond the liver at the porta hepatis, creating the common hepatic duct (CHD). The cystic duct arises from the gallbladder and joins alongside the CHD to form the common bile duct (CBD). The average length of the cystic duct varies between 2 and 4 cm.[24] The typical size of the CBD is often below 11 mm, whereas any measurement beyond 18 mm is regarded as indicative of a problematic condition.[25] The duodenal section of the CBD is surrounded by enlarged longitudinal and circular muscle fibres, commonly referred to as the sphincter of Oddi.[26]

Calot's Triangle: The triangular anatomic area is formed by the common hepatic duct on the inner side, the cystic duct on the outer side, and the cystic artery above it.[24]

Cholecystohepatic triangle is formed by cystic duct on the inner side, a common hepatic duct on the inner side and the inferior border of the liver superiorly, cystic artery is a content of this triangle.[24]

Cystic artery, a branch of the right hepatic artery supplies the gallbladder.

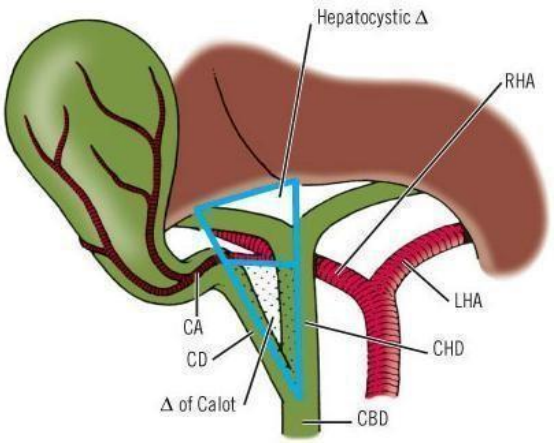


Figure 2: Calot's triangle.[24]

The submucous and subperitoneal layers contain a considerable amount of lymphatic vessels. The cystic glands at the neck of the gallbladder serve as drainage points for these fluids, which then connect with the lymphatic vessels from the head of the pancreas at the CBD. Both the parasympathetic and sympathetic systems provide innervation to the gallbladder and bile ducts.[27,28]

Laparoscopic anatomy

The many anatomical perspectives observed during laparoscopic cholecystectomy, particularly in the vicinity of Calot's triangle, might lead to the misidentification of structures. The Calot's triangle may get deformed by flattening it instead of opening it up, as a result of using various retraction strategies. In addition, the hesitance to carry out a fundus first cholecystectomy, which is more challenging, during a laparoscopic treatment instead of an open procedure, also adds to a certain degree of insufficient visibility of the Calot's triangle.

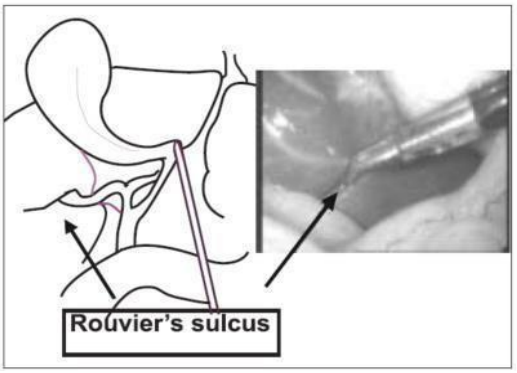


Figure 3: Rouviere's sulcus[29]

Gallstones

The prevalence of gallstone disease exhibits geographical variations. By the age of 75, around 35% of females and 20% of men will have experienced the formation of gallstones.[24] The prevalence of subclinical gallstones is around 10%, and a significant number of individuals will experience symptoms within 5 years of diagnosis.[32]

Classification of gallstones:

	Cholesterol	**Black**	**Brown**
Location	Gallbladder, ducts	Gallbladder, ducts	Ducts
Major constituents	Cholesterol	Bilirubin pigment polymer	Calcium bilirubinate
Consistency	Crystalline with nucleus	Hard	Soft, friable
% Radio-opaque	15%	60%	0%
Associations			
Infection	**Rare**	**Rare**	**Usual**
Other diseases		Haemolysis, Cirrhosis	Chronic partial biliary obstruction

Table 1: Showing classification of gallstones[25]

Symptomatic gallstones:

Chronic Calculous Cholecystitis

It is characterised by persistent inflammation and repeated episodes of biliary colic caused by blockage of the cystic duct with increased fibrosis.[30] Biliary colic, vomiting, nausea, discomfort, and belching are the usual presenting symptoms. Fever and jaundice are rarely seen. The usual therapy for symptomatic individuals is elective laparoscopic cholecystectomy.[33] Diabetic individuals are at an elevated risk for developing acute cholecystitis or gangrenous cholecystitis. As a result, it is strongly recommended that these patients have a timely cholecystectomy.[34]

Acute calculous cholecystitis

In 90-95% of cases, the primary event in acute cholecystitis is the blockage of the cystic duct by gallstones, leading to the enlargement of the gallbladder, resulting in inflammation and swelling of its wall.[35] Commonly, the gallstone becomes

detached, and the inflammation
resolves spontaneously. Right upper quadrant pain, fever, nausea and vomiting are common. Early cholecystectomy, conducted within 2 to 3 days after presentation, is the best approach compared to interval or delayed cholecystectomy, which is carried out 6 to 10 weeks following the start of medical therapy.[30]

Choledocholithiasis

Primary stones originate within the CBD, while secondary stones develop in the gallbladder and then travel into the CBD. The clinical manifestations of CBD blockage, if present, encompass biliary colic accompanied by worsening jaundice, pale stools, and darkening of the urine. If the patient is medically suitable, a timely cholecystectomy following the endoscopic removal of any obstructions in the common bile duct should be done.[30]

Investigations: There are numerous diverse variety of examinations accessible for identifying the presence of gallstones which include: Blood investigations, plain X-ray abdomen, oral cholecystography, cholangiography, ultrasonography (USG), computed tomography (CT), Magnetic Resonance Cholangio-Pancreatography (MRCP), Endoscopic Retrograde Cholangiopancreatography (ERCP) and Hepatobiliary Scintigraphy[35-38]

Management of gallstones

There have been recorded cases when the dissolution of gallstones has been attempted by directly exposing them to solvents and using the percutaneous cholecystolithotomy approach.[39] The objective here is to counteract the excessive concentration of cholesterol in bile. The primary process is enhancing the solubility of cholesterol stones with the use of certain chemicals. The two predominant agents used are chenodeoxycholic acid and ursodeoxycholic acid, which effectively dissolve gallstones by altering the composition of bile and reducing the release of cholesterol in the bile ducts. These compounds facilitate the extraction of cholesterol from stones by micellar solubilisation, promote the creation of a liquid crystalline phase, or do both simultaneously.[40]

Nevertheless, these approaches are not superior compared to oral dissolution, and

laparoscopic cholecystectomy in terms of effectiveness and hence, abandoned. The prevailing medical method for managing gallstones is oral dissolution using ursodeoxycholic therapy, sometimes in conjunction with shock wave lithotripsy.[40-44]

In 1985, Sauerbruch pioneered the utilization of extracorporeal shock-wave lithotripsy for the treatment of gallstone disease. Extracorporeal shock wave lithotripsy (ESWL) involves the application of intense high-pressure waves of sound to the gallstones, causing the stone to break into fragments. The shock wave triggers cavitation on the stone's front surface by exerting simultaneous compressive and tensile stresses, causing the stone to break into fragments, and causing the debris to move from the gall bladder into the gut without obstruction. Fragmentation is influenced by three factors: dimensions, architecture, and microcrystalline structure.[40] Selection criteria of patients for ESWL are normal functioning gallbladder, patency of cystic duct, mild uncomplicated pain, and cholesterol stones.[33] Contraindications are pregnancy, bleeding disorders, patients on anticoagulants and very large stones. Side effects are petechiae on the skin at the location of shock-wave delivery (8%), hematuria (4%) and liver hematomas (<1%), biliary pain, cystic duct obstruction (5%), Biliary pancreatitis (< 2%).[42]

Operative management

Cholecystectomy can be conducted by two approaches: 1. Open surgery and 2. Laparoscopic surgery. The indications are identical for both surgeries:

1. Gallstones that cause symptoms and complications, such as mucocele of the gallbladder, recurrent episodes of biliary pain, biliary pancreatitis, choledocholithiasis including obstruction of the bile ducts outside the liver, and gallstone ileus.

2. Cholecystitis and its related complications consist of: - Acute acalculous cholecystitis, Chronic cholecystitis, Gangrenous cholecystitis, Gallbladder perforation and Empyema gallbladder.

3. Asymptomatic cholelithiasis should only be considered for limited purposes, such as in the case of individuals with diabetes, individuals receiving bariatric surgery,

kidney transplantation and individuals suffering from hemolytic disorders, or gallbladder polyps.[43]

Open cholecystectomy

In certain clinical scenarios, the laparoscopic method poses challenges, and it is prudent to opt for an open cholecystectomy. Clinical problems such as morbid obesity, cirrhosis, prior surgery, portal hypertension, severe obstructive lung disease, and pregnancy are variables that
make laparoscopic cholecystectomy challenging and raise the related risk.[44,45] Furthermore open cholecystectomy is the recommended approach for patients presenting with severe cholecystitis, gallbladder perforation, empyema of the gallbladder, or probable gallbladder malignancy.[45,46]

Complications: Hemorrhage from an artery during cholecystectomy, pulmonary complications, deep-vein thrombosis, cardiovascular problems, wound infection. The mortality rate in open cholecystectomy is approximately 1% and the morbidity rate is around 5%.[48,49]

Mini cholecystectomy is done by giving a subcostal incision, no more than 5 cm. Randomised trials have shown that the results of mini cholecystectomy are comparable with those of the laparoscopic technique. [50]

Percutaneous cholecystostomy is for people who experience problems from acute cholecystitis and require drainage using ultrasound-guided percutaneous drainage utilising a pigtail catheter.[51] This facilitates the reduction of inflammation, and laparoscopic cholecystectomy is scheduled for a future date.

Laparoscopic cholecystectomy

Indications: The indications for laparoscopic cholecystectomy are identical to those for the open operation.

Contraindications: Patients who are not suitable candidates for general anaesthesia, blood clotting disorder, marked portal hypertension, surgeon lacking proficiency in laparoscopic surgery, patients diagnosed with confirmed or suspected advanced gallbladder cancer.

Patients who are likely to require conversion: It is advisable to identify circumstances in which the surgeon should anticipate a challenging laparoscopic treatment and, as a result, should be more inclined to switch to open surgery. It is crucial for the surgeon to be aware of their limitations and promptly identify the appropriate instant to go for an open cholecystectomy from a laparoscopic cholecystectomy. [51,52]

1. Acute cholecystitis - challenging dissection caused by inflammation and adhesion.
2. The presence of several previous surgeries makes it challenging to safely reach the peritoneum.
3. Anomalous anatomy - increased probability of biliary/vascular damage.\

4. During the third trimester of pregnancy, there is an increased likelihood of sustaining uterine damage during access.

5. A liver affected by cirrhosis has an increased probability of experiencing liver damage and bleeding.

6. Obesity - Challenges in reaching and dissecting.

Disadvantages of laparoscopic cholecystectomy: The prevalence of bile duct damage is greater in comparison to the open technique and the duration of operation is extended in comparison to the open technique.

Advantages (over open cholecystectomy): The level of discomfort experienced by the patient after surgery is reduced, the duration of hospitalisation is reduced, the pulmonary function following laparoscopic operation is less reduced compared to the open procedure and the risk of surgical site infection is decreased

Complications:

- Due to trocar wounds and pneumoperitoneum: These include cardiac arrhythmias, gastrointestinal tract perforation, pneumothorax, subcutaneous emphysema, bleeding from the abdominal wall or omentum, solid visceral damage (liver or spleen), and bleeding from the abdominal wall or omentum.
- Bleeding: The avulsion of the cystic artery results in severe bleeding. Research by Ponsky JL found that 0.2% of bleeding cases were brought on by damage to the cystic artery and its branches.

The most significant consequence of laparoscopic and open cholecystectomy is damage to the bile ducts. This problem often results from faulty cautery technique during dissection, incorrect cystic duct identification, and a failure to detect the existence of aberrant ducts.[53]

Stone and bile spillage: Since bile is often sterile, this seldom results in post-operative problems. It doesn't cause any significant issues as long as it is eliminated using suction and irrigation.[54]

Single-incision laparoscopic surgery (SILS): It is accepted as a safe alternative to conventional laparoscopic cholecystectomy for benign gallbladder diseases. A single infra umbilical incision is given and all the necessary instruments are introduced through the same incision site.

The scar is hidden in the umbilical crease. However, it has limited access, making the procedure challenging to the surgeon.

Historical Perspective and Evolution of Laparoscopic Cholecystectomy

Since its introduction in the late 1980s, LC has revolutionized the management of gallbladder disease by offering reduced postoperative pain, shorter hospital stays, and quicker recovery compared to open cholecystectomy. Initially, drainage was commonly employed to prevent bile leakage and intra-abdominal collections; however, advancements in surgical techniques and improved hemostasis have challenged the necessity of routine drainage.

Theoretical Basis for Drain Placement

Proponents of drain placement argue that it serves several theoretical benefits, including:

- Prevention of bile and blood accumulation, reducing the risk of hematoma or biloma formation.
- Early detection of bile leaks or hemorrhage.
- Reduction of postoperative pain and ileus by minimizing fluid collection.

However, routine drainage may also have drawbacks, such as increased risk of infection, prolonged hospital stay, and patient discomfort.

Studies:

The necessity of routine drain placement in LC remains controversial, with studies providing varying conclusions regarding its impact on postoperative outcomes, complications, and recovery. This literature review explores various studies comparing laparoscopic cholecystectomy with and without drainage.

Studies Supporting Drain Placement

1. Agarwal et al.[55] (2010): Reported a decreased incidence of seroma formation in patients with drains, particularly in cases with significant gallbladder bed dissection.

2. Rathi et al.[56] (2012): Reported that patients with subhepatic drains had lower rates of postoperative seroma formation and reduced need for additional interventions.
3. Gupta et al.[57] (2015): Demonstrated that the use of drains in cases with acute cholecystitis reduced postoperative infection rates and provided an early warning system for bile leakage.
4. Surg et al.[58] (2017): Found that selective drainage in complicated laparoscopic cholecystectomy cases led to better post-operative outcomes with reduced reoperation rates.

Studies Against Routine Drain Placement

1. Arslan et al.[59] (2012): This prospective randomized study examined the effect of drain localization on postoperative pain in LC patients. The findings indicated that drain placement contributed significantly to increased postoperative pain, particularly in patients where drains were placed near nerve endings. The study suggested minimizing drain use unless clinically necessary.
2. Sharma & Mittal [60] (2016): A prospective randomized study evaluated the role of routine subhepatic abdominal drainage following uncomplicated LC. The findings suggested that drains do not provide additional safety benefits and may prolong hospitalization and increase patient discomfort. The study recommended selective rather than routine drainage.
3. Yang et al.[61] (2020): A systematic review and meta-analysis protocol was designed to compare LC with and without abdominal drainage in patients with non-

complicated benign gallbladder disease. The study aimed to evaluate the impact on postoperative pain, complications, and hospital stay. The results suggested that routine drain placement might not be necessary for uncomplicated cases as it does not significantly reduce complications while potentially increasing discomfort and hospital stay.

4. Akbar et al.[62] (2022): This study, conducted at Ayub Teaching Hospital, examined the outcomes of LC with and without drain placement. The findings indicated that drainage did not significantly impact postoperative infection rates but was associated with increased postoperative discomfort. The study concluded that avoiding drainage could enhance patient recovery in selected cases.

Meta-Analyses and Systematic Reviews

1. **Cochrane Review [63] (2016):** A meta-analysis of multiple RCTs concluded that routine drainage does not significantly reduce complications but may increase pain and recovery time.
2. **Singh et al. [64] (2020):** In a systematic review, the authors suggested that selective rather than routine drainage should be considered, especially in patients with difficult dissections or intraoperative bile spillage.

MATERIALS AND METHODS

PLACE OF STUDY: Department of General Surgery, Santosh Deemed to be University, Ghaziabad.
STUDY DESIGN: Hospital Based Observational Study.

The sample size formulae used are as follows:

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2 / \kappa)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

$$n_2 = \frac{(\kappa * \sigma_1^2 + \sigma_2^2)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

The notation for the formulae are:
n_1 = sample size of Group 1
n_2 = sample size of Group 2
σ_1 = standard deviation of Group 1
σ_2 = standard deviation of Group 2
Δ = difference in group means
κ = ratio = n_2/n_1
$Z_{1-\alpha/2}$ = two-sided Z value (eg. Z=1.96 for 95% confidence interval).
$Z_{1-\beta}$ = power

DURATION OF STUDY: 18 months.

STUDY POPULATION: Patients undergoing elective laparoscopic cholecystectomy with and without drain placement intraoperatively at Santosh Medical College Hospital.
SAMPLE SIZE: A total of 146 patients were divided into two groups- Group A (73) and Group B (73) on a random basis.
Study Group (A): (n= 73) Subhepatic space was drained by a suction drain which was brought out through mid axillary port.
Control Group (B): (n= 73) Non-drainage of Subhepatic space.

INCLUSION CRITERIA:
- Age group 18-80 years
- Cholelithiasis
- Patients undergoing elective laparoscopic cholecystectomy

EXCLUSION CRITERIA:
- Obstructive Jaundice
- Conversion to open surgery
- Intraoperative haemorrhage
- Intraoperative biliary tract injury
- Intraoperative cholangiogram required
- Performance of any additional procedure

STUDY TOOLS:

1. History: abdominal pain, fever, jaundice, nausea, vomiting.
2. 2.Clinical Examination: Weight, height, palpable lump, tenderness, Murphy's sign.
3. 3.Pre-operative Investigations: CBC, LFT, S.urea, S. creatinine, viral markers, RBS, coagulation profile, Urine routine analysis.
4. Specific Investigations: USG (W/A), MRCP.
5. All Patients were assessed on following parameters on day 0, day 1, day 2 and day 3, postoperatively;

- abdominal pain (Visual Analogue Scale),
- Shoulder pain,
- Surgical site infection,
- Fever,
- Nausea,
- Vomiting,
- Hemorrhage.

6. Duration of postoperative hospital stay.

DATA MANAGEMENT AND STATISTICAL ANALYSIS:

The data was collected and entered in MS Excel 2010. Different statistical analyses were performed using Stata MP-17. The one-sample Kolmogorov-Smirnov test was employed to determine whether the data sets differed from a normal distribution or not. Normally distributed data were analyzed using parametric tests, while non-normally distributed data were analyzed using non-parametric tests. Descriptive statistics were calculated for qualitative and categorical variables. Graphical representations of the variables were shown to understand the results clearly, and associations for the categorical dataset were analyzed using the Chi-Square test. Independent T-tests or Student T-tests were applied to measure the mean difference between two groups. Correlations were estimated to measure the strength of the relationship between two or more quantitative variables. If the p-value was less than 0.05, it was considered statistically significant, and if the p-value was greater than 0.05, then it was considered statistically insignificant.

Sample Size For Comparing Two Means

Input Data

Confidence Interval (2-sided)	95%
Power	80%
Ratio of sample size (Group 2/Group 1)	1

	Group 1	Group 2	Difference*
Mean	2.96	2.26	0.7
Standard deviation	1.5	1.5	
Variance	2.25	2.25	

Sample size of Group 1	73
Sample size of Group 2	73
Total sample size	146

*Difference between the means

Results from OpenEpi, Version 3, open source calculator--SSMean
Print from the browser with ctrl-P
or select text to copy and paste to other programs.

RESULTS

RESULTS

Table 1: Distribution according to Age and BMI.

	Group	Mean	Lower	Upper	SD	P-value
Age	A	50.1	48.6	51.6	6.493	< .001
	B	35.0	33.5	36.5	6.256	
BMI	A	22.6	22.3	22.9	1.421	< .001
	B	26.6	26.4	26.8	0.940	

The above table represents the distribution of participants according to Age and BMI across two groups, A and B. Group A had a significantly higher mean age of 50.1 years (SD = 6.493, 95% CI: 48.6–51.6) compared to Group B, which had a mean age of 35.0 years (SD = 6.256, 95% CI: 33.5–36.5), with a P-value of < 0.001, indicating a statistically significant difference. Similarly, the mean BMI in Group A was 22.6 (SD = 1.421, 95% CI: 22.3–22.9), which was significantly lower than that of Group B, which had a mean BMI of 26.6 (SD = 0.940, 95% CI: 26.4–26.8), also with a P-value of < 0.001.

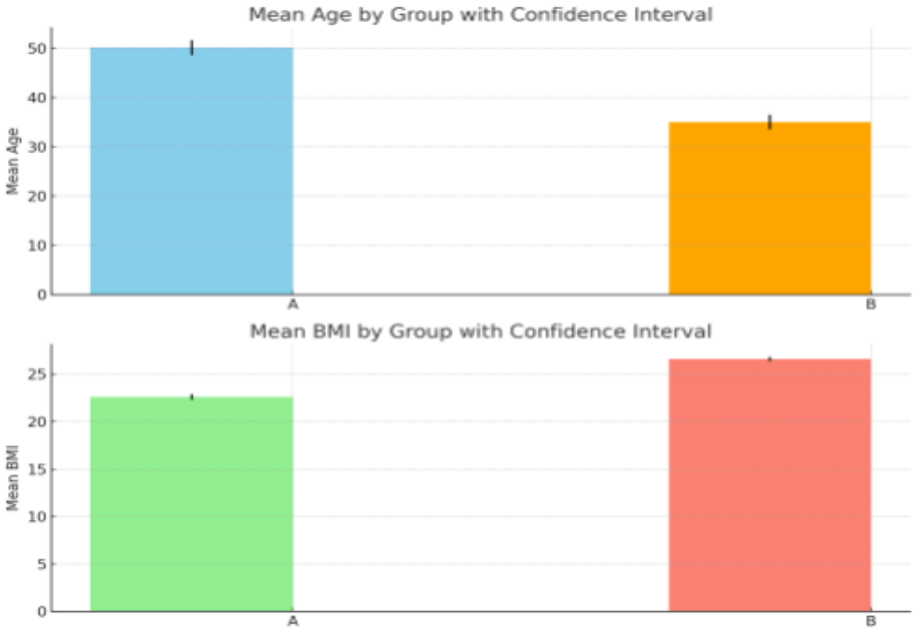


Table 2: Distribution according to gender.

Gender	Group A	Group B	Total	P-value
Male	46 (63.0%)	42 (57.5%)	88(60.3%)	0.499
Female	27 (37.0%)	31 (42.5%)	58 (39.7%)	
Total	73(100.0%)	73 (100.0%)	146(100.0%)	

The above table represents the distribution of participants according to gender in Group A and Group B. In Group A, 46 participants (63.0%) were male and 27 (37.0%) were female, while in Group B, 42 participants (57.5%) were male and 31 (42.5%) were female. Overall, out of the total 146 participants, 88 (60.3%) were male and 58 (39.7%) were female. The difference in gender distribution between the two groups was not statistically significant, as indicated by the p-value of 0.499.

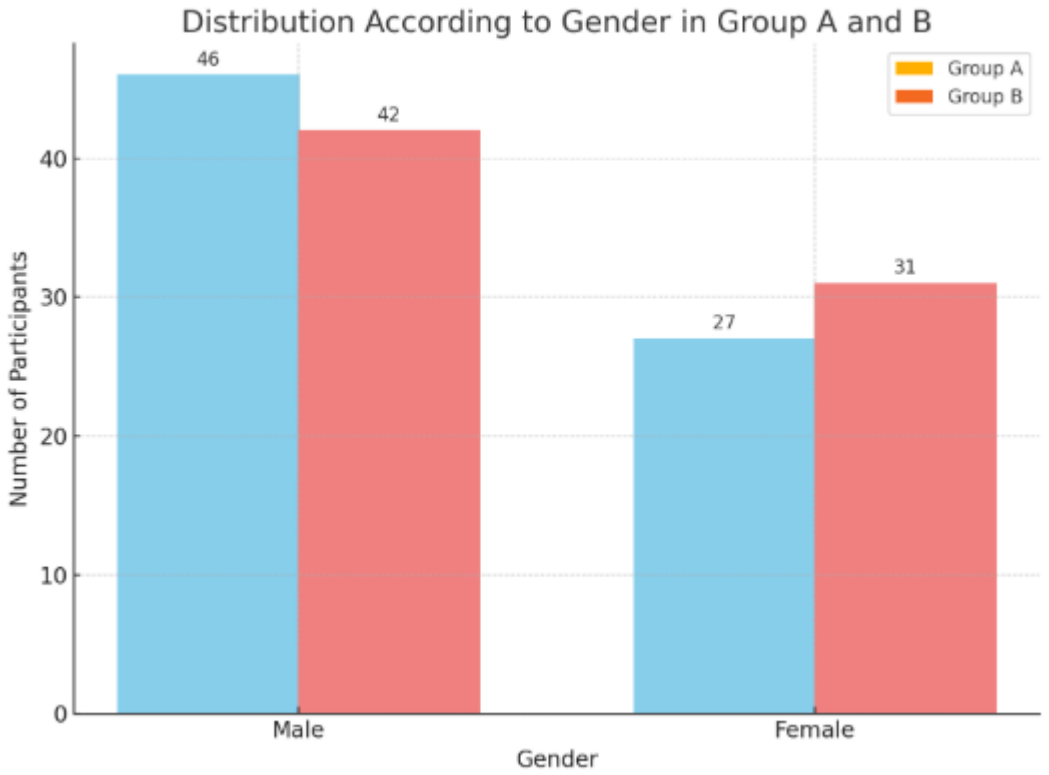


Table 3: Distribution according to Symptoms.

Symptoms	Group A	Group B	Total	p-value
Abdominal Pain				0.023
Yes	73(100.0%)	68 (93.2%)	141 (96.6%)	
No	0(0.0%)	5(6.8%)	5(3.4%)	
Fever				0.021
Yes	16 (21.9%)	6 (8.2%)	22 (15.1%)	
No	57(78.1%)	67(91.8%)	124(84.9%)	
Nausea				0.025
Yes	13(8.9%)	6(4.1%)	19(13.0%)	
No	60(41.1%)	67(45.9%)	127(87.0%)	
Vomiting				0.029
Yes	5(3.4%)	11(7.5%)	16(10.9%)	
No	68(46.6%)	62(42.5%)	130(89.1%)	

The above table represents the distribution of symptoms among patients in Group A and Group B, with corresponding p-values indicating the statistical significance of the differences observed. Abdominal pain was reported by all patients in Group A (100%) and by 93.2% in Group B, with a statistically significant difference (p = 0.023). Fever was present in 21.9% of Group A and 8.2% of Group B patients (p = 0.021), while nausea was reported by 8.9% in Group A and 4.1% in Group B (p = 0.025). Vomiting was observed in 3.4% of Group A and 7.5% of Group B (p = 0.029). All the symptoms showed statistically significant differences between the two groups, suggesting variability in clinical presentation.

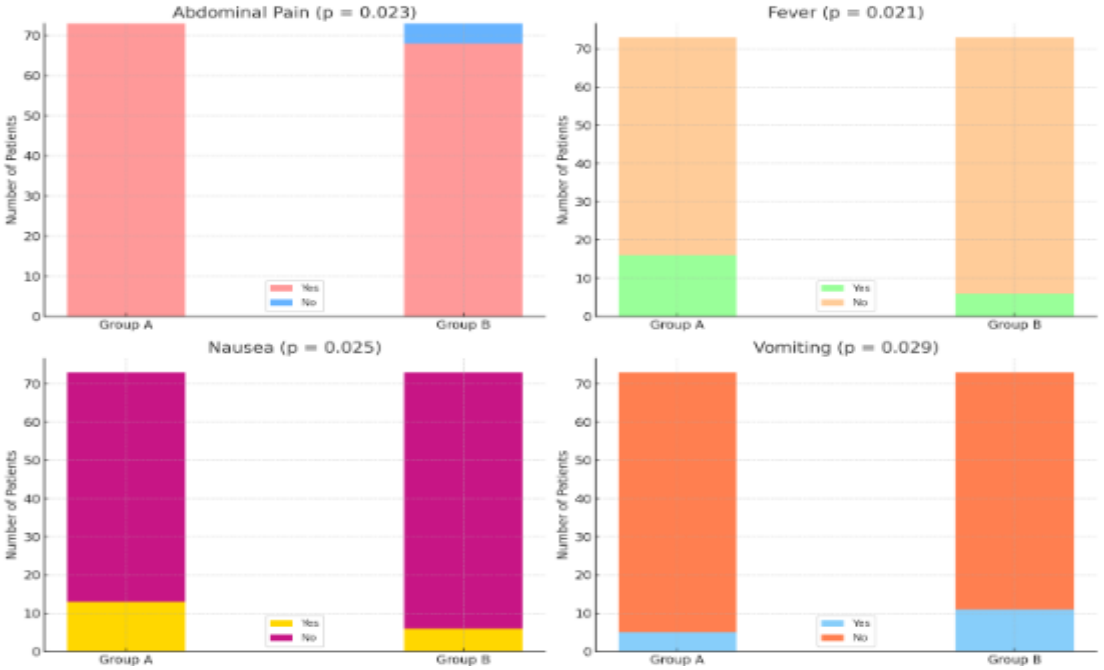


Table 4: Distribution according to examination.

	Group A	Group B	Total
Palpable Lump			
Yes	4 (2.7%)	5 (3.4%)	9 (3.1%)
No	69 (47.3%)	68 (46.6%)	137 (46.9%)
Murphy's Sign			
Yes	16 (11.0%)	4 (2.7%)	20 (6.8%)
No	57 (39.0%)	69 (47.3%)	126 (43.2%)

The above table represents the distribution of patients in Group A and Group B based on clinical examination findings, specifically the presence of a palpable lump and Murphy's sign. A palpable lump was present in 4 patients (2.7%) in Group A and 5 patients (3.4%) in Group B, with a total of 9 patients (3.1%) showing this finding. In contrast, the majority of patients had no palpable lump, accounting for 69 (47.3%) in Group A and 68 (46.6%) in Group B, totaling 137 patients (46.9%). Murphy's sign was positive in 16 patients (11.0%) in Group A and 4 patients (2.7%) in Group B, with an overall total of 20 patients (6.8%). The remaining 57 patients (39.0%) in Group A and 69 patients (47.3%) in Group B, amounting to 126 patients (43.2%), did not exhibit a positive Murphy’s sign.

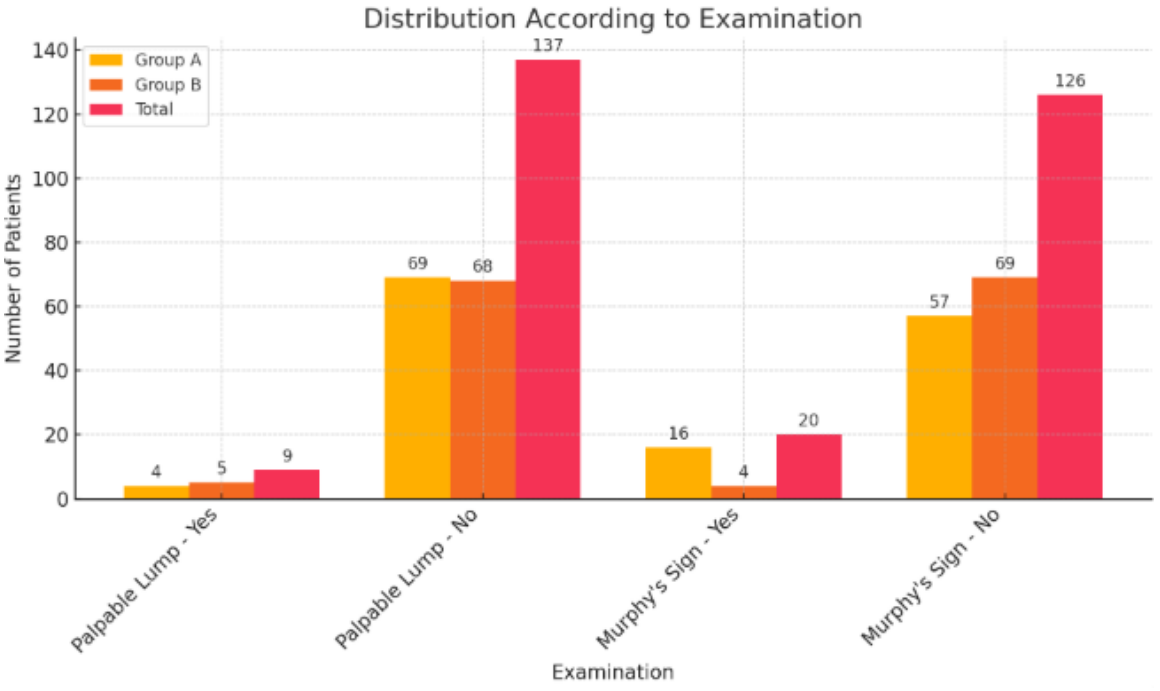


Table 5: Distribution according to Preoperative Investigation.

Variable	Group	Mean	Lower 95% CI	Upper 95% CI	SD	Range	Skewness	SE
TLC	A	10.258	9.849	10.667	1.753	5.790	-0.20478	0.281
	B	8.427	7.955	8.898	2.020	6.750	-0.00409	0.281
S. Bilirubin	A	0.748	0.688	0.807	0.255	1.100	0.70394	0.281
	B	0.695	0.649	0.741	0.197	1.100	0.30201	0.281
ALP	A	134.795	104.932	164.657	127.991	841	3.71636	0.281
	B	104.808	89.842	119.774	64.145	373	3.21324	0.281
S. Creatinine	A	0.805	0.749	0.862	0.240	0.900	0.10048	0.281
	B	0.804	0.742	0.866	0.267	1.000	0.31529	0.281
RBS	A	135.644	121.098	150.189	62.342	251	1.15717	0.281
	B	127.178	117.844	136.512	40.004	198	0.39061	0.281
INR	A	1.090	1.058	1.123	0.140	0.500	0.61631	0.281
	B	1.090	1.058	1.123	0.140	0.500	0.67929	0.281

The above table represents the distribution of various preoperative investigations between Group A and Group B, including parameters such as TLC, Serum Bilirubin, ALP, Serum Creatinine, RBS, and INR. Group A exhibited a higher mean TLC (10.258) compared to Group B (8.427), with both groups showing minimal skewness. Serum Bilirubin levels were slightly higher in Group A (0.748) than in Group B (0.695), with a positive skew in both groups. ALP values were significantly higher in Group A (mean: 134.795) than in Group B (104.808), with considerable variability and marked positive skewness. Serum Creatinine levels were nearly identical in both groups (0.805 vs. 0.804), suggesting no notable difference. Random Blood Sugar (RBS) levels were also higher in Group A (135.644) as compared to Group B (127.178), with greater variability and skewness in Group A. The INR values remained the same for both groups (1.090), with a slight increase in skewness for Group B. The table also includes statistical measures such as standard deviation, range, skewness, and standard error for comprehensive analysis.

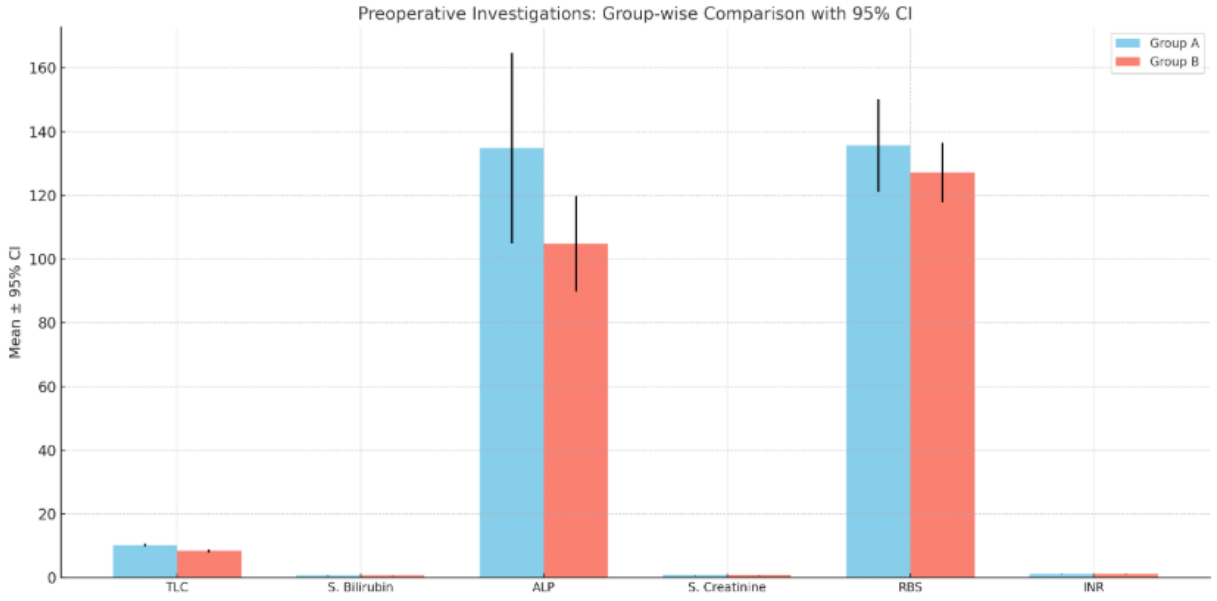


Table 6: Distribution according to Viral Markers

Viral Marker	Group A	Group B	Total
Hepatitis B			
Negative	73 (50.0%)	71 (48.6%)	144 (98.6%)
Positive	0 (0.0%)	2 (1.4%)	2 (1.4%)
Hepatitis C			
Negative	72 (49.3%)	71 (48.6%)	143 (97.9%)
Positive	1 (0.7%)	2 (1.4%)	3 (2.1%)
HIV			
Negative	72 (49.3%)	70 (47.9%)	142 (97.3%)
Positive	1 (0.7%)	3 (2.1%)	4 (2.7%)

The above table represents the distribution of viral markers among participants in Group A and Group B. For Hepatitis B, all individuals in Group A were negative, while 2 individuals (1.4%) in Group B tested positive, making the overall positivity rate 1.4%. Regarding Hepatitis C, 1 individual in Group A and 2 individuals in Group B tested positive, accounting for a total of 3 cases (2.1%). In the case of HIV, 1 participant from Group A and 3 from Group B were positive, resulting in an overall HIV positivity rate of 2.7%. The majority of participants in both groups tested negative for all three viral markers.

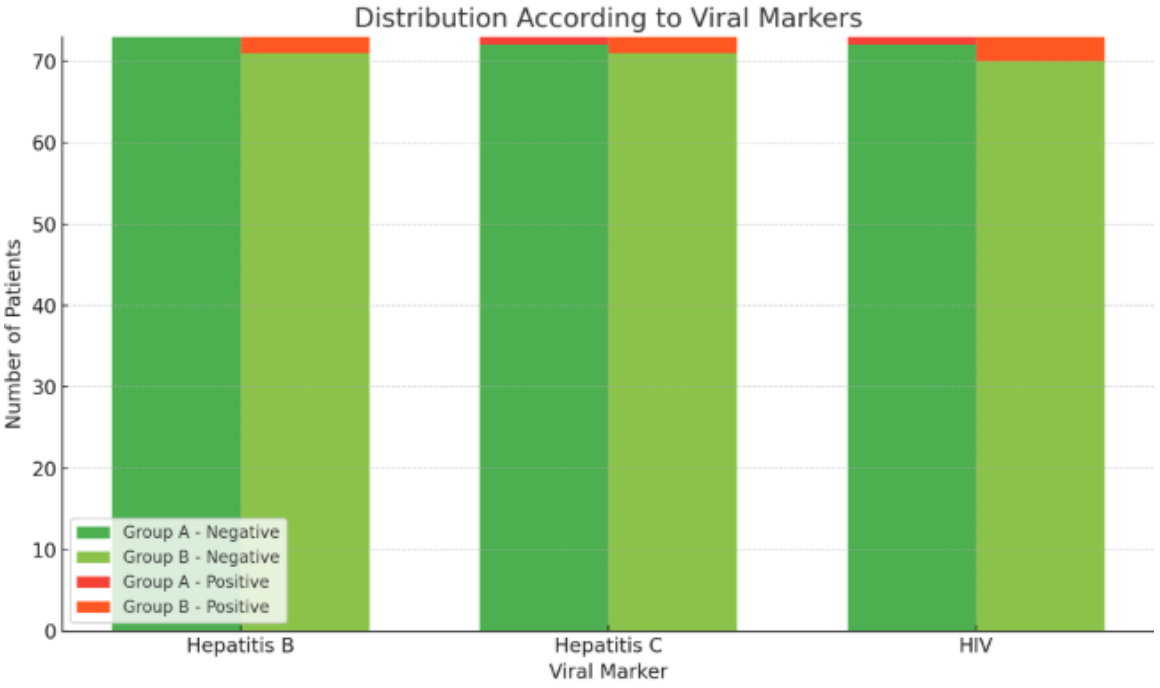


Table 7: Distribution according to radiological investigation

Variable	Group A	Group B	Total
USG			
Yes	73 (50.0%)	73 (50.0%)	146 (100.0%)
MRCP			
No	65 (44.5%)	70 (47.9%)	135 (92.5%)
Yes	8 (5.5%)	3 (2.1%)	11 (7.5%)

The above table represents the distribution of patients in Group A and Group B according to radiological investigations. Ultrasonography (USG) was performed in 146 patients, with an equal number of cases (73 each) in both Group A and Group B, accounting for 50.0% in each group. Magnetic Resonance Cholangiopancreatography (MRCP) was not performed in the majority of patients, with 65 (44.5%) in Group A and 70 (47.9%) in Group B, totaling 135 cases (92.5%). Only 11 patients (7.5%) underwent MRCP, with 8 (5.5%) in Group A and 3 (2.1%) in Group B.

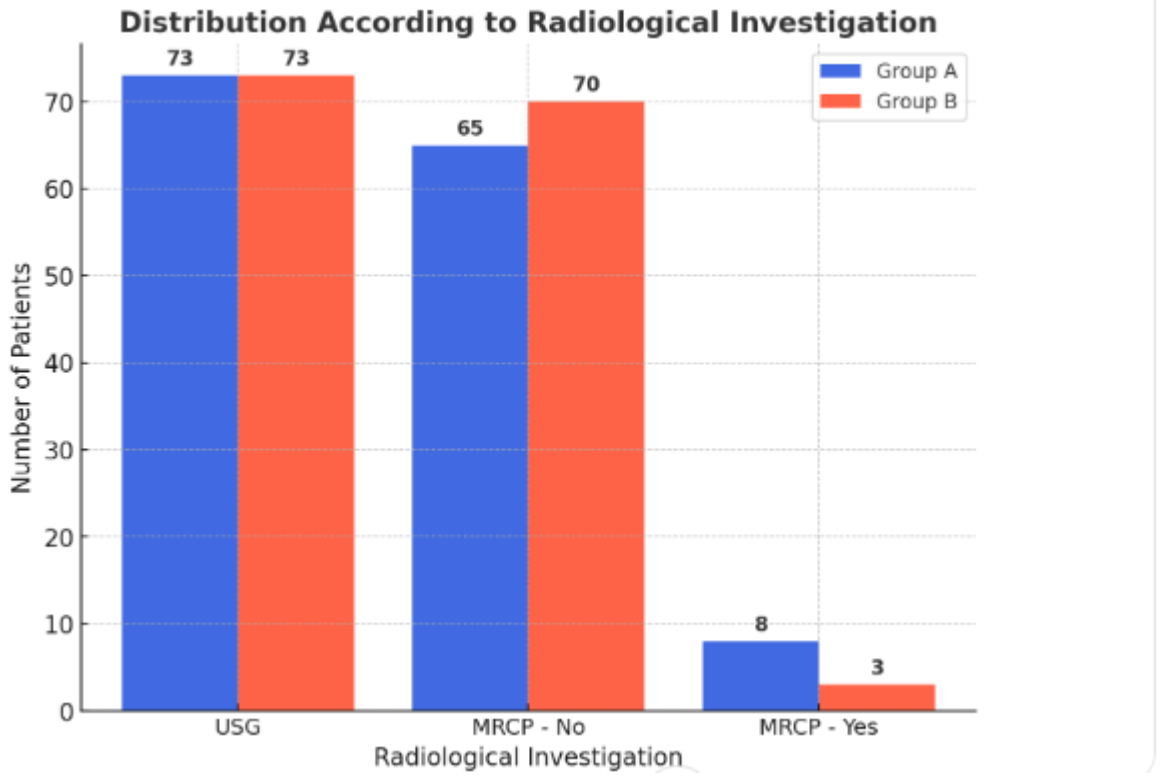


Table 8: Distribution according to Drain Removal

Drain Removal Day	Group A	Group B	Total
2	23 (15.8%)	0 (0.0%)	23 (15.8%)
3	34 (23.3%)	0 (0.0%)	34 (23.3%)
4	16 (11.0%)	0 (0.0%)	16 (11.0%)
N/A	0 (0.0%)	73 (50.0%)	73 (50.0%)

The above table represents the distribution of patients in Group A and Group B according to the day of drain removal. In Group A, drains were removed on day 2 in 23 patients (15.8%), on day 3 in 34 patients (23.3%), and on day 4 in 16 patients (11.0%). In contrast, none of the patients in Group B had their drains removed on these days, and all 73 patients (50.0%) in Group B had "Not Applicable" (N/A) status for drain removal, indicating that no drain was placed or removal was not required. This highlights a clear difference in postoperative drain management between the two groups.

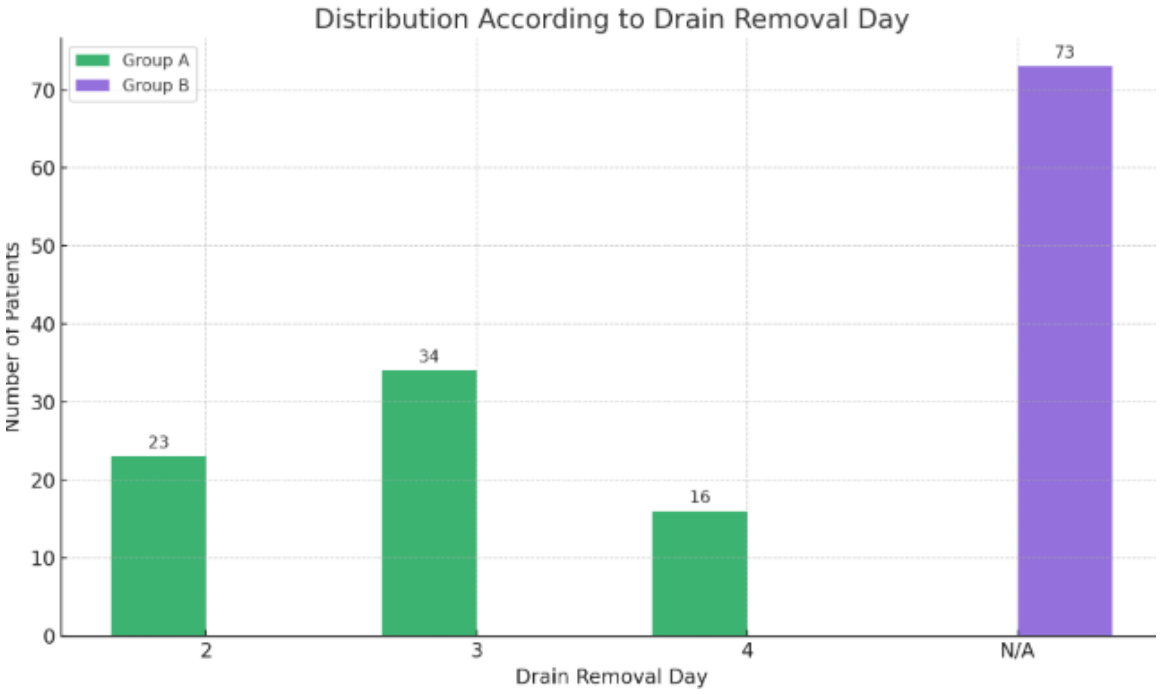


Table 9: Distribution according to operating time and length of hospital stay

Variable	Group	Mean	Lower 95% CI	Upper 95% CI	SD	Range	Skewness	SE
Operating Time (Mins)	A	123.11	116.58	129.64	27.996	90	0.0118	0.281
	B	81.18	77.12	85.24	17.399	57	-0.0821	0.281
Length of Hospital Stay	A	3.19	2.99	3.40	0.877	3	0.3745	0.281
	B	2.97	2.82	3.12	0.645	2	0.0246	0.281

The above table represents the distribution of two variables—operating time and length of hospital stay—across two groups (A and B). Group A had a higher mean operating time of 123.11 minutes (95% CI: 116.58–129.64) compared to Group B with a mean of 81.18 minutes (95% CI: 77.12–85.24). The standard deviation and range were also higher in Group A (SD: 27.996, Range: 90) than in Group B (SD: 17.399, Range: 57), indicating greater variability in operating time in Group A. For the length of hospital stay, Group A had a slightly longer mean duration of 3.19 days (95% CI: 2.99–3.40) compared to Group B with 2.97 days (95% CI: 2.82–3.12). The standard deviation and range were also marginally higher in Group A (SD: 0.877, Range: 3) than in Group B (SD: 0.645, Range: 2). Skewness values for both variables across groups were close to zero, suggesting near-normal distribution.

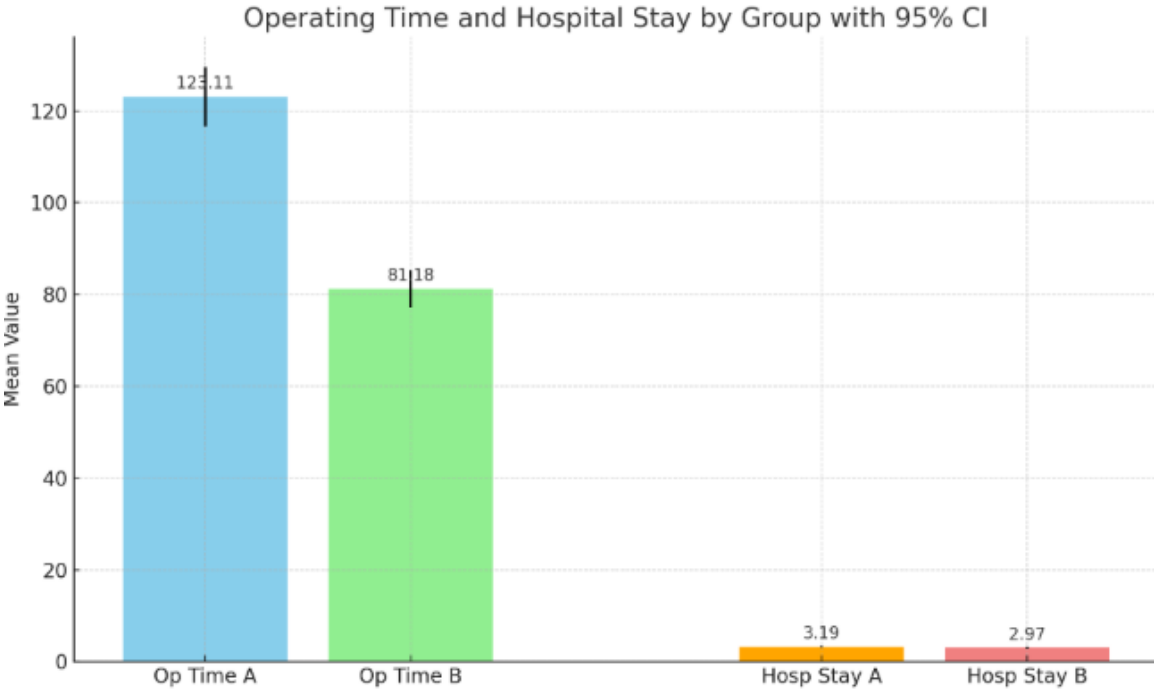


Table:10 Abdominal Pain (VAS) - Day 0

VAS score	Group A	Group B	Total
4	1 (0.7%)	1 (0.7%)	2 (1.4%)
5	14 (9.6%)	42 (28.8%)	56 (38.4%)
6	40 (27.4%)	24 (16.4%)	64 (43.8%)
7	17 (11.6%)	6 (4.1%)	23 (15.8%)
8	1 (0.7%)	0 (0.0%)	1 (0.7%)

The above table represents the distribution of abdominal pain scores based on the Visual Analog Scale (VAS) on Day 0 among two groups, Group A and Group B. A majority of participants in both groups reported moderate pain levels, with the most common VAS score being 6, observed in 40 participants (27.4%) from Group A and 24 participants (16.4%) from Group B, totaling 64 (43.8%). A VAS score of 5 was the next most frequent, reported by 14 (9.6%) in Group A and 42 (28.8%) in Group B, contributing to a total of 56 (38.4%). Higher pain scores such as 7 were noted in 17 (11.6%) of Group A and 6 (4.1%) of Group B. Very few participants experienced either low (VAS 4) or high (VAS 8) pain scores, with only 2 (1.4%) and 1 (0.7%) cases respectively across both groups.

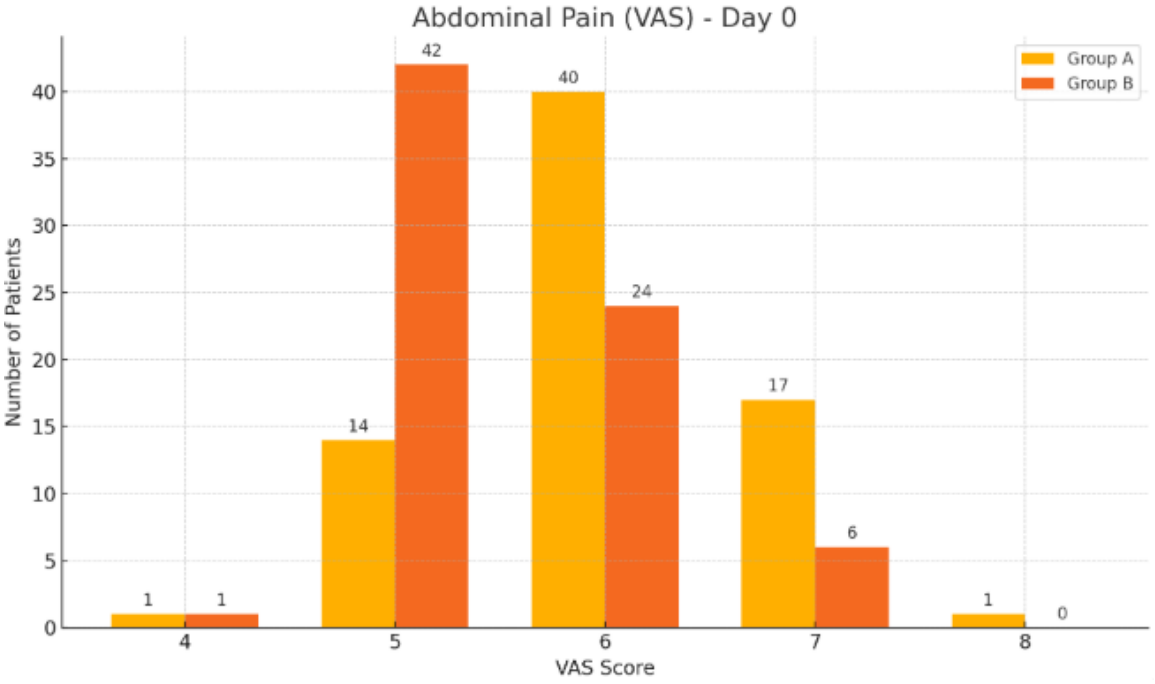


Table:11 Abdominal Pain (VAS) - Day 1

VAS score	Group	Counts	% of Total
2	A	1	0.7%
	B	9	6.2%
3	A	13	8.9%
	B	52	35.6%
4	A	39	26.7%
	B	12	8.2%
5	A	17	11.6%
	B	0	0.0%
6	A	2	1.4%
	B	0	0.0%
7	A	1	0.7%
	B	0	0.0%

The above table represents the distribution of abdominal pain intensity, measured using the Visual Analog Scale (VAS), on Day 1 among two groups, A and B. In Group A, the most common VAS score was 4, reported by 26.7% of the participants, followed by a score of 5 in 11.6%, and score 3 in 8.9%. Group B, on the other hand, showed a higher concentration of participants with a VAS score of 3 (35.6%), followed by score 2 (6.2%) and score 4 (8.2%). Notably, Group A had higher scores ranging from 5 to 7, which were absent in Group B, indicating that participants in Group A experienced relatively more severe abdominal pain on Day 1 compared to those in Group B.

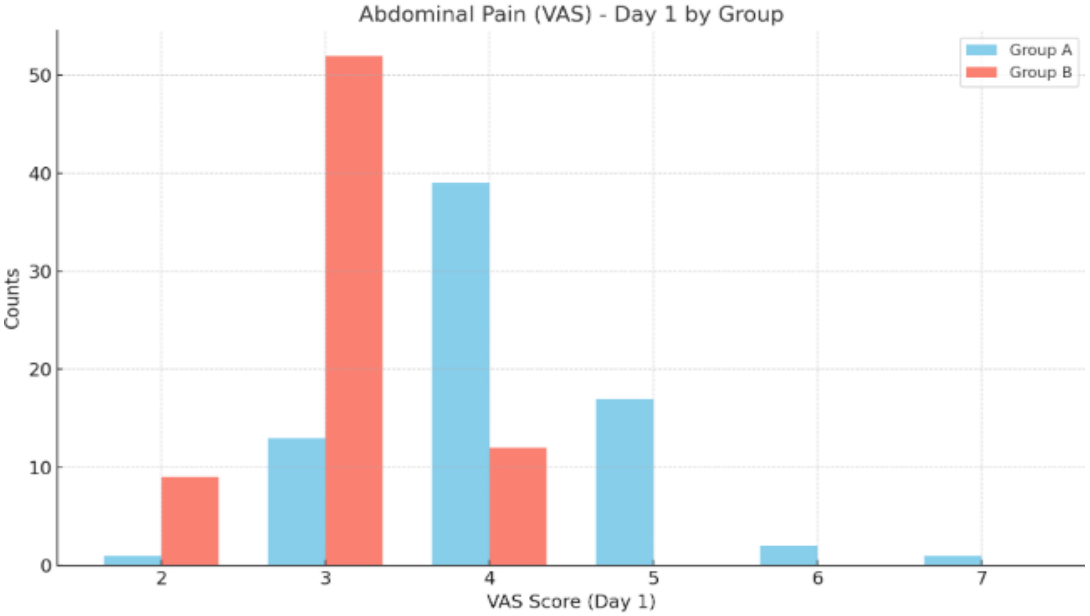


Table:12 Abdominal Pain (VAS) - Day 2

VAS score	Group	Counts	% of Total
1	A	0	0.0%
	B	6	4.1%
2	A	0	0.0%
	B	59	40.4%
3	A	27	18.5%
	B	8	5.5%
4	A	44	30.1%
	B	0	0.0%
5	A	2	1.4%
	B	0	0.0%

The above table represents the distribution of abdominal pain scores on Day 2, measured using the Visual Analog Scale (VAS), among two groups—Group A and Group B. In Group A, the majority of participants (30.1%) reported a VAS score of 4, followed by 18.5% reporting a score of 3, and a minimal 1.4% with a score of 5; notably, no participants in Group A reported scores of 1 or 2. In contrast, Group B showed the highest proportion (40.4%) of participants reporting a VAS score of 2, followed by 4.1% with a score of 1, and 5.5% with a score of 3; no participants in Group B reported scores of 4 or 5. This suggests that participants in Group B experienced lower levels of abdominal pain compared to those in Group A on Day 2.

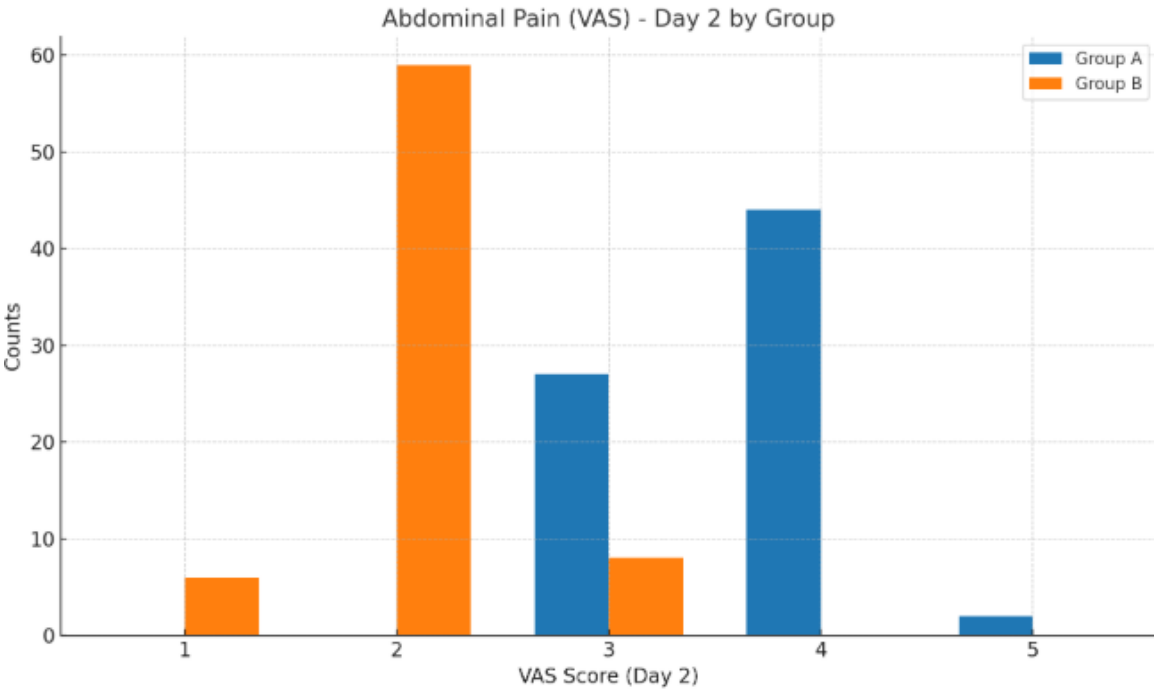


Table:13 Abdominal Pain (VAS) Day 3

VAS score	Group A	Group B	Total
1	0 (0.0%)	9 (6.2%)	9 (6.2%)
2	14 (9.6%)	63 (43.2%)	77 (52.7%)
3	55 (37.7%)	1 (0.7%)	56 (38.4%)
4	4 (2.7%)	0 (0.0%)	4 (2.7%)

The above table represents the distribution of abdominal pain scores on Day 3, measured using the Visual Analogue Scale (VAS), in Group A and Group B. The majority of patients in Group A reported a VAS score of 3 (37.7%), followed by a score of 2 (9.6%) and 4 (2.7%), with no patients reporting a score of 1. In contrast, most patients in Group B reported a lower VAS score of 2 (43.2%), followed by a score of 1 (6.2%), and only a single patient (0.7%) had a score of 3, with none reporting a score of 4. Overall, the total number of patients experiencing mild to moderate pain (VAS score 2) was highest (52.7%), suggesting that abdominal pain was more prevalent and severe in Group A compared to Group B on Day 3.

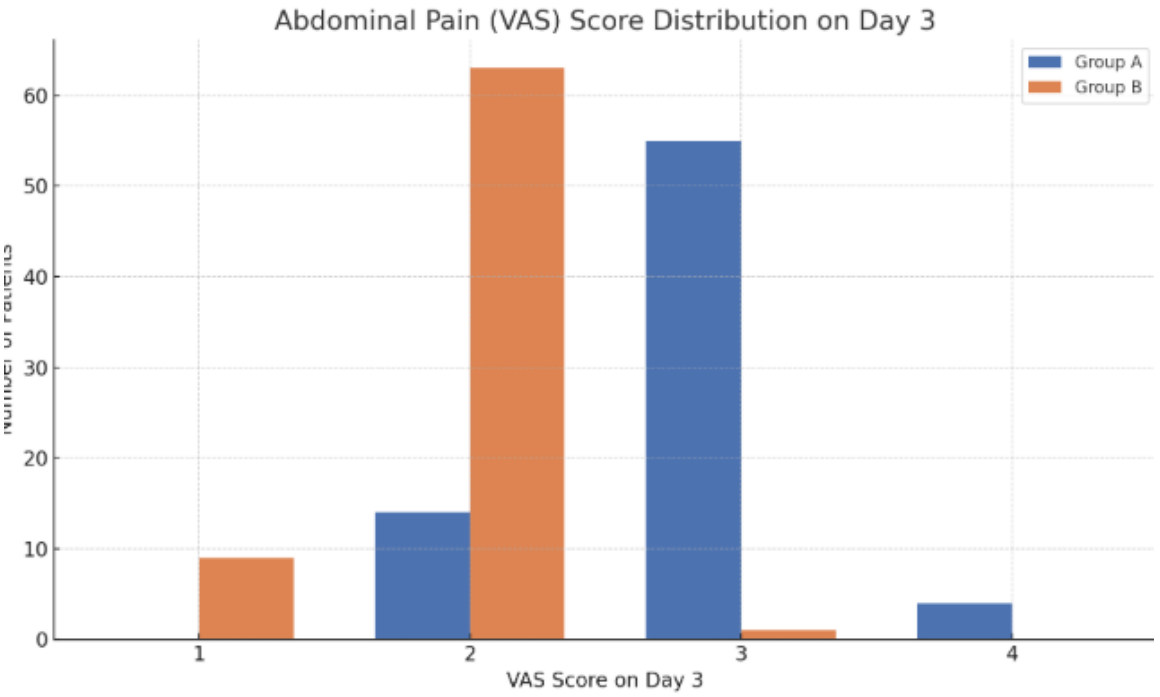


Table:14 Shoulder Pain (VAS) Day 0

VAS score	Group A	Group B	Total
2	2 (1.4%)	0 (0.0%)	2 (1.4%)
3	22 (15.1%)	54 (37.0%)	76 (52.1%)
4	30 (20.5%)	17 (11.6%)	47 (32.2%)
5	16 (11.0%)	2 (1.4%)	18 (12.3%)
6	3 (2.1%)	0 (0.0%)	3 (2.1%)

The above table represents the distribution of shoulder pain intensity on Day 0, measured using the Visual Analog Scale (VAS), among two groups (Group A and Group B). The most common VAS score in Group A was 4, reported by 30 patients (20.5%), whereas in Group B, the majority had a VAS score of 3, reported by 54 patients (37.0%). Lower pain scores (VAS 2 and 3) were more prevalent in Group B, while higher scores (VAS 4, 5, and 6) were more frequently reported in Group A. Notably, VAS scores of 6 were only observed in Group A (2.1%). Overall, a total of 76 patients (52.1%) experienced moderate pain (VAS score 3), making it the most common score across both groups.

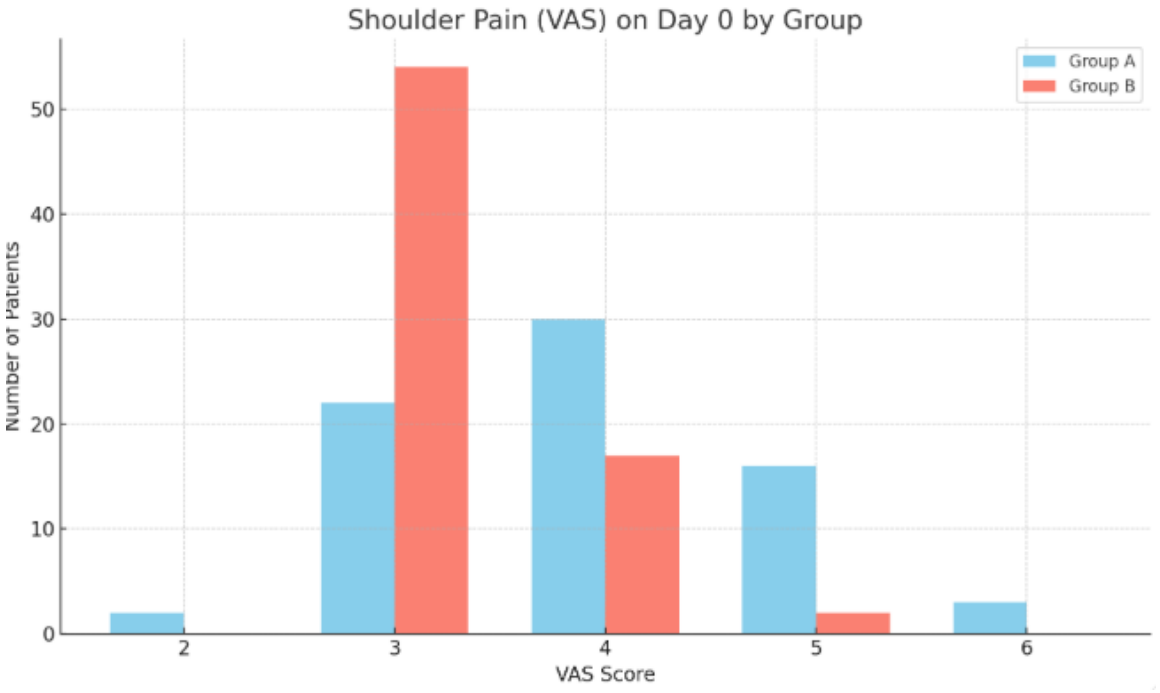


Table:15 Shoulder Pain (VAS) Day 1

VAS score	Group A	Group B	Total
0	0 (0.0%)	29 (19.9%)	29 (19.9%)
1	17 (11.6%)	20 (13.7%)	37 (25.3%)
2	56 (38.4%)	24 (16.4%)	80 (54.8%)

The above table represents the distribution of shoulder pain intensity, assessed using the Visual Analogue Scale (VAS), on Day 1 among patients in Group A and Group B. A VAS score of 0, indicating no pain, was reported by 29 patients (19.9%) in Group B, whereas none in Group A reported no pain. A mild pain score of 1 was observed in 17 patients (11.6%) from Group A and 20 patients (13.7%) from Group B, totaling 37 patients (25.3%). The majority of patients reported a VAS score of 2, indicating moderate pain, with 56 patients (38.4%) in Group A and 24 patients (16.4%) in Group B, making up a total of 80 patients (54.8%). This suggests that shoulder pain was generally more prevalent and severe in Group A compared to Group B on Day 1.

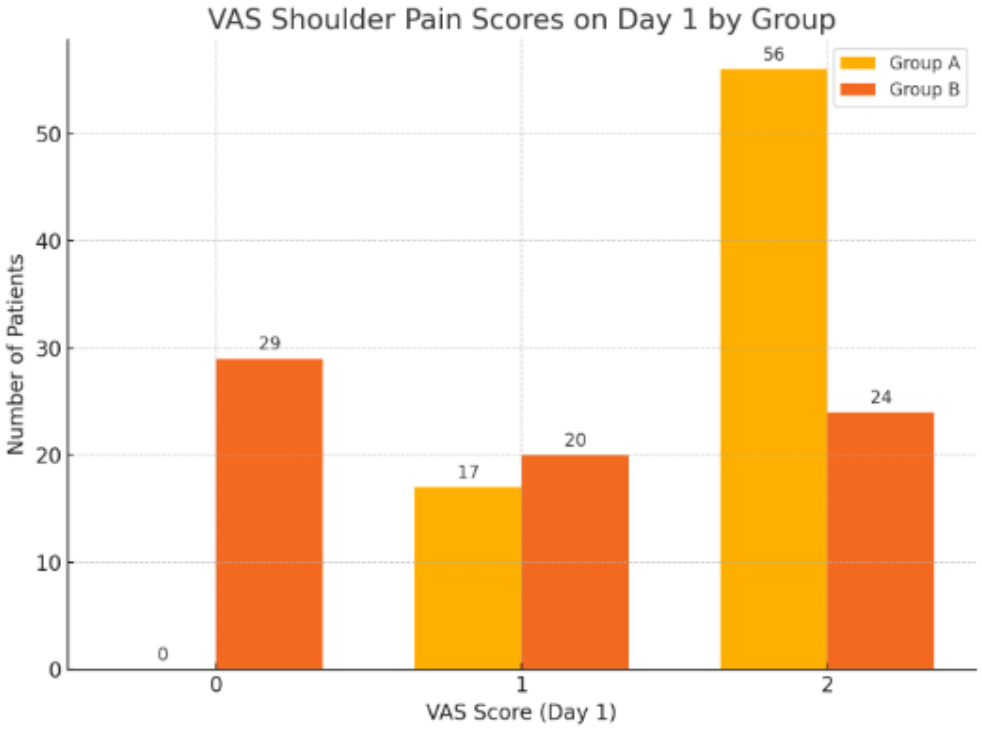


Table:16 Shoulder Pain (VAS) Day 2

VAS score	Group A	Group B	Total
0	34 (23.3%)	48 (32.9%)	82 (56.2%)
1	25 (17.1%)	20 (13.7%)	45 (30.8%)
2	14 (9.6%)	5 (3.4%)	19 (13.0%)

The above table represents the distribution of shoulder pain assessed using the Visual Analogue Scale (VAS) on Day 2 among two groups, Group A and Group B. A total of 82 participants (56.2%) reported no pain (VAS score 0), with 34 (23.3%) from Group A and 48 (32.9%) from Group B. Mild pain (VAS score 1) was observed in 45 participants (30.8%), comprising 25 (17.1%) from Group A and 20 (13.7%) from Group B. Moderate pain (VAS score 2) was reported by 19 participants (13.0%), including 14 (9.6%) from Group A and 5 (3.4%) from Group B. Overall, Group B showed a higher proportion of participants with no shoulder pain compared to Group A on Day 2.

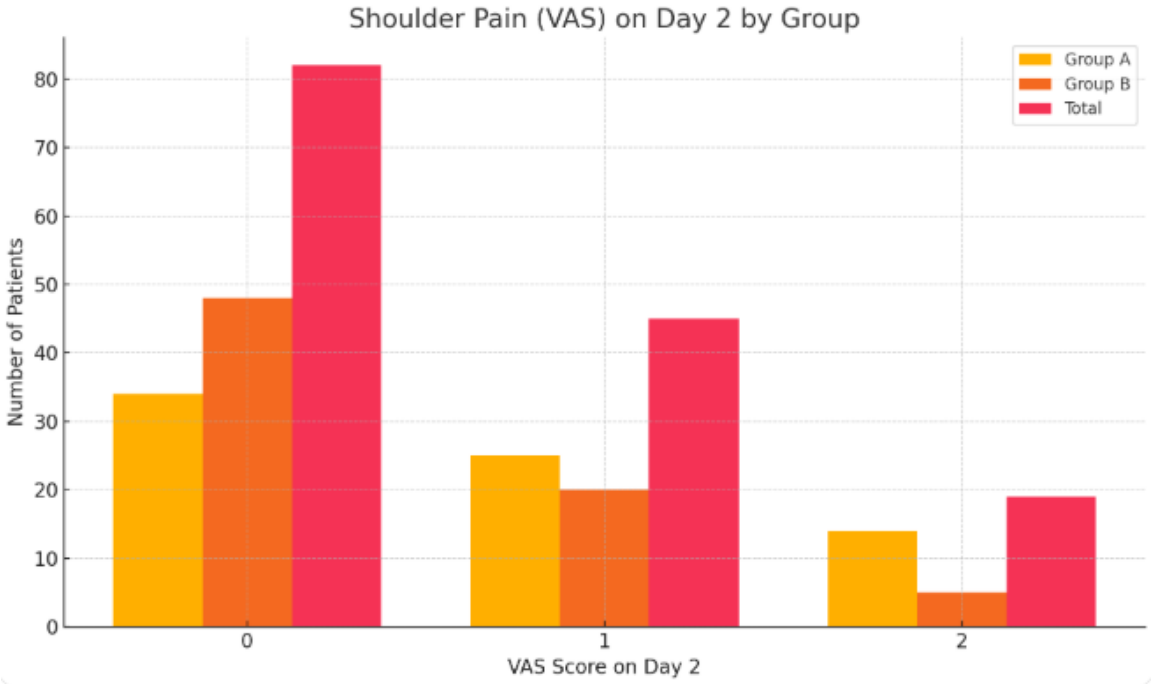


Table:17 Shoulder Pain (VAS) Day 3

VAS score	Group A	Group B	Total
0	67 (45.9%)	71 (48.6%)	138 (94.5%)
1	6 (4.1%)	2 (1.4%)	8 (5.5%)

The above table represents the comparison of shoulder pain assessed using the Visual Analogue Scale (VAS) on Day 3 between Group A and Group B. A majority of patients in both groups reported no shoulder pain, with 67 patients (45.9%) in Group A and 71 patients (48.6%) in Group B scoring 0 on the VAS, accounting for a total of 138 patients (94.5%). Mild shoulder pain with a VAS score of 1 was reported by 6 patients (4.1%) in Group A and 2 patients (1.4%) in Group B, totaling 8 patients (5.5%). This indicates that the incidence of shoulder pain on Day 3 was minimal in both groups.

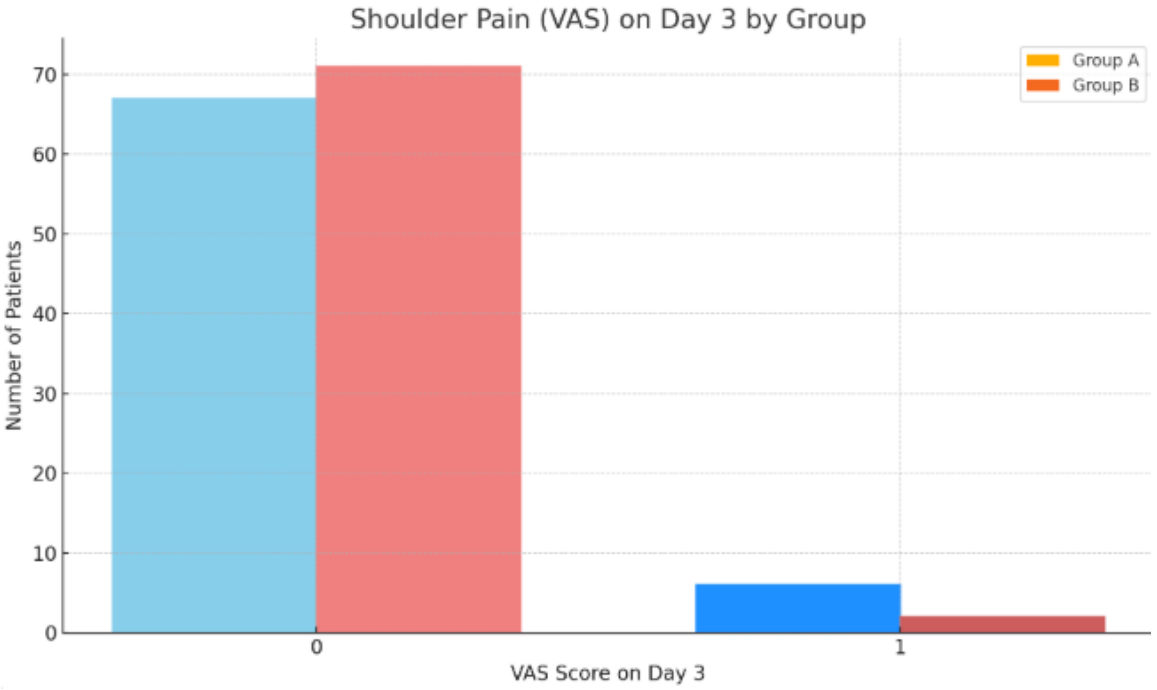
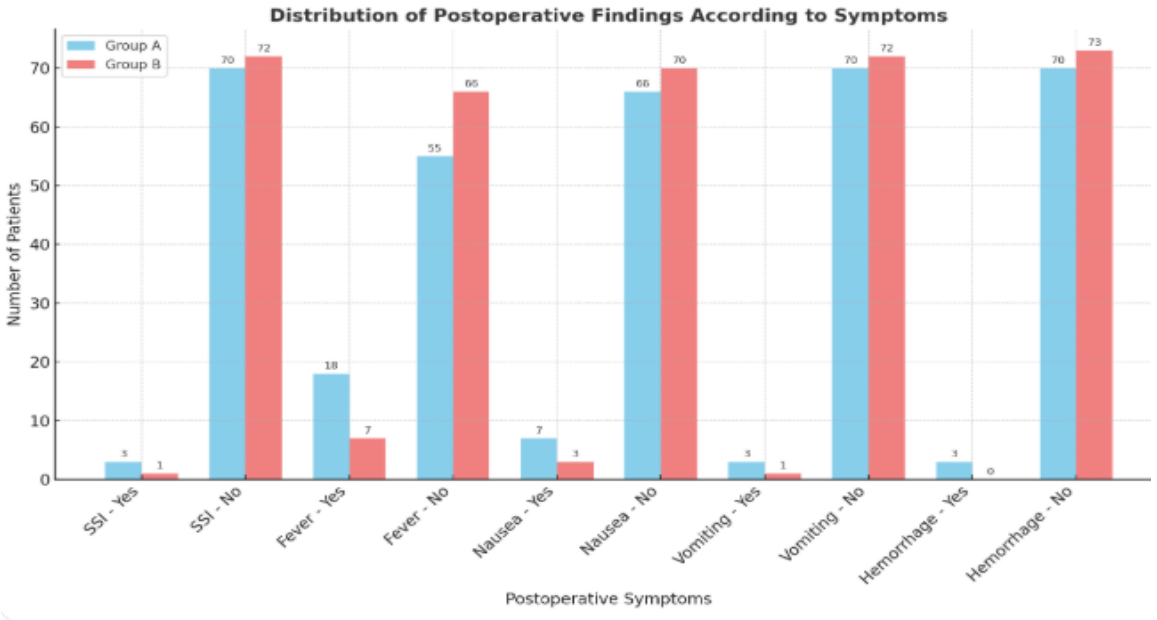


Table:18 Distribution of postoperative findings according to symptoms

	Group A	Group B	Total
SSI			
No	70 (47.9%)	72 (49.3%)	142 (97.3%)
Yes	3 (2.1%)	1 (0.7%)	4 (2.7%)
Fever			
Yes	18 (12.3%)	7 (4.8%)	25 (17.1%)
No	55 (37.7%)	66 (45.2%)	121 (82.9%)
Nausea			
Yes	7 (4.8%)	3 (2.1%)	10 (6.8%)
No	66 (45.2%)	70 (47.9%)	136 (93.2%)
Vomiting			
Yes	3 (2.1%)	1 (0.7%)	4 (2.7%)
No	70 (47.9%)	72 (49.3%)	142 (97.3%)
Hemorrhage			
No	70 (47.9%)	73 (50.0%)	143 (97.9%)
Yes	3 (2.1%)	0 (0.0%)	3 (2.1%)

The above table represents the distribution of postoperative findings according to symptoms in Group A and Group B. Surgical site infection (SSI) was observed in 2.7% of the total patients, with 3 cases in Group A and 1 in Group B, while the remaining 97.3% had no SSI. Fever was reported in 17.1% of patients, with a higher occurrence in Group A (12.3%) compared to Group B (4.8%). Nausea was experienced by 6.8% of patients, with 7 cases in Group A and 3 in Group B. Vomiting was reported by 2.7% of the total patients, predominantly in Group A (2.1%) compared to 0.7% in Group B. Hemorrhage occurred in 2.1% of patients, all from Group A, with no cases in Group B, while the majority (97.9%) did not experience hemorrhage.



DISCUSSION

The present study was conducted in the Department of General Surgery at Santosh Deemed to be University, Ghaziabad, as a hospital-based observational study over a duration of 18 months. The aim of the study was to assess the effect of drainage tube use versus no drainage tube use in patients undergoing elective laparoscopic cholecystectomy. The study population comprised patients who underwent elective laparoscopic cholecystectomy with or without intraoperative drain placement at Santosh Medical College Hospital. The primary objective was to compare the length of hospital stay between the two groups. Additionally, the study aimed to evaluate and compare postoperative complications on day 0, day 1, day 2, and day 3, which included abdominal pain assessed using the Visual Analogue Scale (VAS), shoulder pain, drain site infection, wound infection, fever, nausea, vomiting, and haemorrhage. Through this comparative evaluation, the study intended to determine the necessity and impact of routine drain placement in uncomplicated laparoscopic cholecystectomy procedures.

Below is a comparison and analysis of key findings from our data, contextualized by studies supporting and opposing drain placement.

Demographic and Baseline Characteristics:

- Age and BMI:

In the present study, patients were divided into two groups: Group A (with drain placement) and Group B (without drain placement), and the distribution of age and BMI was analyzed to assess baseline characteristics. The mean age of patients in Group A was 50.1 years (SD = 6.493), while that in Group B was significantly lower, with a mean of 35.0 years (SD = 6.256). This difference was statistically significant with a P-value of <0.001, indicating that patients in the drain group were generally older than those in the no-drain group. The study done by **Sharma & Mittal[60] (2016)** on uncomplicated laparoscopic cholecystectomies involved a broader age range, including younger individuals, and did not see significant benefits from routine drain placement. The study suggested that younger, healthier patients may recover just as well without drains.

Over 60% below 50 years of age, with 38% being under 40 years and 30% between 40 to 49 years. This suggests that a significant proportion of individuals requiring surgical intervention fall within the younger to middle-aged adult group. The proportion gradually declined with increasing age, as only 19% of patients were in the 50–59 year range and

13% were aged 60 years or older. This trend could reflect better health-seeking behavior or more active lifestyles in the younger age groups, or possibly the increasing risk of comorbidities and surgical contraindications with advancing age, leading to underrepresentation of elderly patients in operative cases. Systematic review by **Yang et al.**[61] **(2020)** analyzed a broad patient population with non-complicated benign gallbladder disease, meaning that the patients included in this review were likely younger and less likely to need drains routinely. This aligns with our study's finding that younger patients (Group B) did not benefit from drains.

Similarly, the mean Body Mass Index (BMI) was found to be significantly different between the two groups. Group A had a lower mean BMI of 22.6 (SD = 1.421), whereas Group B had a higher mean BMI of 26.6 (SD = 0.940), with the difference also being statistically significant ($P < 0.001$). These findings suggest that patients in the non-drain group were younger and had a higher BMI compared to those in the drain group. This baseline variation is important to consider, as age and BMI can influence postoperative recovery and complication rates. Therefore, while comparing outcomes between the two groups, such differences were taken into account to avoid confounding effects on the overall interpretation of the results. For **Yang et al.[61] (2020)** BMI was not directly linked to the need for drains, but it is known that higher BMI can increase the risk of complications like infections and delayed recovery, which is something that might explain why drains were used selectively rather than routinely.

When evaluating the Body Mass Index (BMI) of the patients, we observed that the majority (69%) fell within the overweight category (BMI 25–29.9), while 18% had a normal BMI (less than 25), and 13% were classified as obese (BMI ≥30). These findings indicate that overweight individuals constituted the largest group undergoing surgery in our study. This may be due to the well-established association between increased BMI and various surgical conditions such as hernias, cholelithiasis, or orthopedic issues, where excess weight contributes to pathogenesis and symptomatic presentation. In **Gupta et al.[57] (2015)** study, obesity is a known risk factor for gallbladder disease, which may explain why drains were used in patients with a higher BMI. However, our study suggests that even in the presence of higher BMI, the use of drains did not confer significant advantages in uncomplicated cases.

- Gender Distribution:

In the present study, both groups (Group A – with drain and Group B – without drain), comprised an equal number of patients (n=73 in each group), totaling 146 patients. The gender distribution revealed that in Group A, 63.0% were males and 37.0% were females, while in Group B, 57.5% were males and 42.5% were females. The p-value of 0.499 indicated that the difference in gender distribution between the two groups was not statistically significant, suggesting that gender did not act as a confounding variable in the outcome analysis. This finding is consistent with several studies including **Gupta et al.[57] (2015), Sharma & Mittal [60] (2016), and Akbar et al.[62] (2022)**, which found that gender did not significantly affect the decision to place drains or the postoperative outcomes.

Physical Examination:

On physical examination, palpable abdominal lumps were found in a small proportion of patients (2.7% in Group A and 3.4% in Group B), with no significant difference noted. However, Murphy's sign was positive in 11.0% of patients in the drain group compared to only 2.7% in the no-drain group. Although not statistically tested here, this might indicate a higher rate of localized tenderness or inflammation in the drain group, possibly due to irritation or pressure from the drain itself.

Laboratory and Radiological Investigations:

In the present study, we evaluated preoperative laboratory and radiological findings in patients undergoing elective laparoscopic cholecystectomy, comparing two groups—those with drain placement (Group A) and those without drain placement (Group B). The objective was to assess whether there were any significant preoperative differences between the two groups that could influence postoperative outcomes. When comparing Total Leukocyte Count (TLC), Group A had a higher mean TLC of 10.26×10^9/L (SD = 1.75) as compared to Group B, which had a mean of 8.43×10^9/L (SD = 2.02). This suggests that patients in Group A may have had a higher inflammatory status preoperatively. Despite this, the range and standard deviation in both groups were comparable, indicating overlapping values among many patients.

Serum bilirubin levels were slightly higher in Group A (mean = 0.75 mg/dL) than in Group B (mean = 0.70 mg/dL), but both values fell within the normal physiological range, indicating that most patients did not present with significant obstructive jaundice.

Alkaline phosphatase (ALP) levels showed a notable difference between the groups. Group

A had a mean ALP of 134.80 IU/L (SD = 127.99), while Group B had a mean of 104.81 IU/L (SD = 64.15). The wide range and high standard deviation in both groups suggest variable hepatic enzyme levels, possibly reflecting subclinical biliary pathology or differing durations of gallstone disease.

Serum creatinine was nearly identical in both groups (0.805 mg/dL in Group A vs. 0.804 mg/dL in Group B), confirming that renal function was preserved and comparable preoperatively.

Similarly, Random Blood Sugar (RBS) levels were slightly higher in Group A (mean = 135.64 mg/dL) compared to Group B (127.18 mg/dL), though both values are not substantially raised to suggest any significant difference in glycemic control.

INR values were the same in both groups (mean = 1.09), indicating stable coagulation profiles preoperatively and eliminating coagulopathy as a confounding factor for drain placement.

Regarding viral markers, most patients in both groups tested negative for Hepatitis B, Hepatitis C, and HIV. Only a small number tested positive: 2 patients for Hepatitis B (both in Group B), 3 for Hepatitis C (1 in Group A, 2 in Group B), and 4 for HIV (1 in Group A, 3 in Group B). The low prevalence of viral infections across both groups indicates minimal risk of transmission-related complications or confounding hepatic factors.

Radiological investigations showed that all patients (100%) underwent ultrasonography (USG), confirming gallbladder pathology before surgery. MRCP was performed in 11 patients—8 in Group A and 3 in Group B—likely due to clinical suspicion of common bile duct stones or biliary obstruction. The slightly higher number of MRCPs in Group A may reflect a marginally more complex preoperative biliary picture in that group. The slightly higher use of **MRCP** in Group A suggests that drain placement might be associated with more complex biliary cases, aligning with findings from **Gupta et al.[57] (2015)**, who indicated that drains might be used in more complicated cases to reduce the risk of bile leakage.

We did not find any relevant studies which relate to Distribution according to preoperative radiological investigations and distribution according to Viral Markers.

Studies such as **Agarwal et al.[55] (2010)** and **Gupta et al.[57] (2015)** support the idea that

drains may be beneficial in certain high-risk surgeries, such as complicated cholecystectomies, by reducing the risk of infection and seroma formation. However, studies like **Sharma & Mittal[60] (2016)** and **Yang et al.[61] (2020)** argue that routine drain placement does not significantly reduce complications and may actually increase patient discomfort and prolong hospitalization. This is reflected in our data, which shows increased postoperative discomfort and longer recovery times in Group A.

Operating Time and Hospital Stay:

- Operating time was longer in **Group A** (mean of 123.11 minutes vs. 81.18 minutes in **Group B**). When evaluating the operating time, a notable difference was observed between the two groups. Group A had a higher mean operating time of 123.11 minutes with a standard deviation (SD) of 27.996, whereas Group B had a significantly lower mean operating time of 81.18 minutes with an SD of 17.399. This suggests that the placement of a drain may have contributed to a longer surgical duration, possibly due to the additional steps required for proper positioning and fixation of the drain. This is consistent with the findings in **Akbar et al.[62] (2022)**, which suggested that drains may increase the complexity of surgery.
- In terms of the length of hospital stay, patients in **Group A** also had a slightly longer duration of admission. The mean hospital stay in Group A was 3.19 days (SD = 0.877), compared to 2.97 days (SD = 0.645) in **Group B**. Although the difference in hospital stay may seem small, it highlights a potential clinical benefit in terms of earlier discharge when drains are avoided. This could be attributed to reduced postoperative discomfort, fewer complications such as drain site pain or infection, and better overall recovery in the non-drain group. This finding supports studies such as **Sharma & Mittal [60] (2016)**, which concluded that drains often lead to prolonged hospital stays, likely due to the discomfort, risk of infection, and the need for drain care.

Postoperative Symptoms and Complications:

1. Pain:

When analyzing postoperative symptoms, the postoperative pain assessment across **Day 0** to **Day 3** clearly indicated that **patients without a drain (Group B)** reported lower levels

of both abdominal and shoulder pain throughout the postoperative period. This suggests that the use of a drain may contribute to an increased perception or incidence of postoperative pain. These results align with findings from **Akbar et al.[62] (2022)**, who found that drains increased postoperative discomfort.

Discussion of Postoperative Pain Findings: Day-wise Analysis

In this section, we will discuss the findings related to postoperative abdominal and shoulder pain in patients undergoing elective laparoscopic cholecystectomy, comparing those with drain placement (Group A) and without drain placement (Group B). Postoperative pain was assessed using the **Visual Analogue Scale (VAS)** on **Day 0**, **Day 1**, **Day 2**, and **Day 3** following surgery.

Day 0 (Immediate Postoperative Period): Abdominal Pain

On **Day 0**, moderate pain (VAS score 6) was reported most frequently by patients in both groups. Specifically:

- **Group A (with drain placement)**: 27.4% of patients reported a VAS score of 6.
- **Group B (without drain placement)**: 16.4% of patients reported a VAS score of 6.

However, **Group B** had a higher percentage of patients reporting a VAS score of 5 (28.8%) compared to **Group A** (9.6%). Interestingly, more patients in **Group A** experienced **severe pain** (VAS scores 7 and 8), with 11.6% of patients reporting VAS score 7 and 0.7% reporting VAS score 8. In contrast, **Group B** had fewer patients reporting higher pain scores, with only 4.1% reporting VAS score 7 and none reporting VAS score 8. This suggests that **Group A (with drains)** had higher postoperative pain immediately following surgery, which could be due to the physical presence of the drain causing discomfort, or the surgical trauma associated with drain placement.

These findings are consistent with **Nayak SR et al.[65] (2019)**, who also found that while immediate postoperative pain (Day 0) was similar between both groups, patients with drains reported slightly higher pain scores, although this difference was not statistically significant.

Day 1: Early Postoperative Period

By **Day 1**, there was a noticeable reduction in pain severity in both groups, as expected during the early recovery phase. However, the difference between the groups remained:

- In **Group B**, 35.6% of patients reported mild pain (VAS score 3), compared to only 8.9% in **Group A**.
- In **Group A**, higher pain scores such as **VAS scores 4** (26.7%) and **VAS score 5** (11.6%) were more common compared to **Group B** (8.2% and 0%, respectively).
- **Group A** was the only group with patients reporting VAS scores of 6 and 7.

This suggests that **patients with drains** continued to experience more discomfort compared to those without drains, even as pain generally decreased in both groups. The higher pain scores in **Group A** are likely attributed to the physical presence of the drain, which may irritate the abdominal cavity, peritoneal lining, or incisional site, and could also contribute to a longer duration of pain.

Day 2: Recovery Phase

By **Day 2**, pain had significantly reduced in both groups, with the trend continuing towards better recovery for patients without drains:

- **Group B** had a majority of patients reporting very low pain scores, with 40.4% scoring VAS 2 and 4.1% scoring VAS 1.
- In contrast, **Group A** reported slightly higher pain scores, with 30.1% of patients reporting VAS score 4 and 18.5% reporting VAS score 3. No patients in **Group A** reported pain scores of 1 or 2.

This further supports the notion that **Group B** (no drain) experienced a faster and more consistent recovery with respect to abdominal pain. The absence of a drain likely led to less irritation and discomfort during the recovery period, contributing to a more comfortable experience.

Day 3: Postoperative Recovery and Resolution of Abdominal Pain

By **Day 3**, abdominal pain had resolved in a significant proportion of patients in both

groups, but the differences between groups remained evident:

- **Group A**: A total of 37.7% of patients reported a VAS score of 3, and only 9.6% reported VAS score 2.
- **Group B**: The majority (43.2%) of patients in **Group B** reported a VAS score of 2, and 6.2% reported a VAS score of 1.

Interestingly, **Group B** had fewer patients reporting moderate pain, with only 0.7% of patients reporting VAS score 3. This indicates that patients without a drain had significantly lower levels of postoperative abdominal pain, which could be due to the absence of the physical drain and associated discomfort.

Shoulder Pain: Day 0 to Day 3

Shoulder pain, often a result of diaphragmatic irritation caused by insufflation CO_2 during laparoscopic surgery, was also assessed.

- **Day 0**: On the day of surgery, more patients in **Group B** (non-drain) reported moderate shoulder pain (VAS score 3) compared to **Group A** (with drain). Specifically:
    - **Group B**: 37% of patients reported moderate shoulder pain (VAS score 3).
    - **Group A**: 15.1% of patients reported moderate shoulder pain.
- Higher pain scores (VAS 4 and 5) were more common in **Group A**, with 20.5% of patients reporting VAS score 4 and 11.0% reporting VAS score 5, compared to 11.6% and 1.4%, respectively, in **Group B**. This suggests that **Group A** (with drains) experienced more intense shoulder pain during the immediate postoperative period, potentially due to the additional discomfort caused by the drain. However, this was not universally observed, as some patients in **Group B** also reported significant shoulder pain.
- **Day 1**: By **Day 1**, the **Group B** (without drain) showed a significant reduction in shoulder pain. For instance:
    - 19.9% of patients in **Group B** reported **complete relief** (VAS score 0), while none in **Group A** experienced full relief.

More patients in **Group A** continued to report shoulder pain, with 38.4% of patients reporting mild pain (VAS score 2).

- These findings suggest that patients without a drain had a quicker resolution of shoulder pain, possibly due to less irritation from the peritoneal stretch caused by the drain tube. The absence of the drain likely contributed to less diaphragmatic irritation and therefore less shoulder discomfort.

- **Day 2 and Day 3**: By **Day 2**, **Group B** experienced further reduction in shoulder pain, with 32.9% of patients reporting no pain (VAS score 0), compared to 23.3% in **Group A**. On **Day 3**, the majority of patients in both groups reported complete resolution of shoulder pain (VAS score 0), with 48.6% of patients in **Group B** and 45.9% of patients in **Group A** reporting no shoulder pain. However, **Group B** had a slightly higher percentage of patients reporting no pain.

2. Fever:

Fever was also significantly more common in the drain group, affecting 21.9% of patients, compared to only 8.2% in the non-drain group (p=0.021). This finding may point toward a higher inflammatory response or infection risk associated with the presence of a foreign body like a drain. This is consistent with findings from **Agarwal et al.[55] (2010)**, which suggested that drains might lead to a higher risk of infection and inflammatory response.

3. Nausea and Vomiting:

Similarly, nausea was observed in 13 patients in Group A (8.9%) and in 6 patients in Group B (4.1%), with a p-value of 0.025, again showing statistical significance. Vomiting was more prevalent in the no-drain group (7.5%) as compared to 3.4% in the drain group, with a p-value of 0.029. These findings indicate variable patterns of gastrointestinal discomfort across groups, possibly influenced by individual patient responses to surgery or anesthesia, rather than the drain use alone suggesting that drains may increase gastrointestinal discomfort, although this is a secondary symptom, not the primary driver of recovery **(Yang et al.[61] 2020)**.

4. Surgical Site Infection:

The incidence of surgical site infection (SSI) was slightly higher in Group A, with 3 patients (2.1%) developing SSI compared to only 1 patient (0.7%) in Group B. This

suggests that the use of a drain may be associated with a slightly increased risk of infection at the surgical site, possibly due to an additional breach in the sterile barrier (**Agarwal et al.,[55] 2010)**.

5. Hemorrhage:

Interestingly, hemorrhage was noted only in the drain group, with 3 cases (2.1%) reported in Group A and none in Group B. This may indicate that drain placement could be associated with a slightly higher chance of minor bleeding, possibly from the insertion site or manipulation during surgery. Overall, the majority of patients in both groups had uneventful postoperative recovery, with no significant complications. Unfortunately, there was no other concrete data in comparable studies.

SUMMARY AND CONCLUSION

Summary

The present study titled “Laparoscopic Cholecystectomy with and without Drainage: A Hospital-Based Observational Study” was conducted over a span of 18 months at the Department of General Surgery, Santosh Deemed to be University, Ghaziabad, with the aim to evaluate the impact of drain placement in elective laparoscopic cholecystectomy. A total of 146 patients were randomly divided into two groups—Group A (with drainage) and Group B (without drainage), each consisting of 73 patients. This study primarily focused on the assessment of postoperative complications, length of hospital stay, abdominal and shoulder pain (using VAS scores), and other symptoms such as fever, nausea, vomiting, and surgical site infections.

The demographic profile revealed that the mean age of patients in Group A was significantly higher at 50.1 years compared to 35.0 years in Group B. Similarly, BMI was lower in Group A (22.6) as compared to Group B (26.6), which was statistically significant. This suggests that older patients with relatively lower BMI were more frequently managed with drainage, possibly reflecting surgeons’ preferences influenced by perceived risk of complications in this cohort. Gender distribution showed no significant difference between the groups, maintaining balance in the sample characteristics.

In terms of clinical presentation, abdominal pain was almost universally present, though slightly higher in the drainage group (100% vs 93.2%). Fever, nausea, and vomiting were observed more commonly in Group A. For instance, fever was present in 21.9% of patients in Group A and only in 8.2% in Group B. Similar trends were observed in nausea (8.9% vs 4.1%) and vomiting (3.4% vs 7.5%). These differences, though modest, reached statistical significance and suggest that drain placement may be associated with increased incidence of certain postoperative symptoms.

The study also revealed a notable difference in operating time and hospital stay. Group A had a significantly longer mean operating time (123.11 minutes) compared to Group B (81.18 minutes), indicating additional time for drain placement and possibly more complex surgeries. The average hospital stay was also slightly longer in Group A (3.19 days) than in Group B (2.97 days), suggesting that drain usage may contribute to delayed discharge, perhaps due to monitoring for drain output or management of drain-related issues.

VAS scores assessing abdominal pain from Day 0 to Day 3 showed a consistent pattern of higher pain levels in the drainage group. On Day 0, a VAS score of 6 was most commonly reported in Group A (40 cases), whereas the majority in Group B reported a score of 5 or less. By Day 3, 37.7% of Group A patients still reported a VAS score of 3, whereas most Group B patients had pain scores reduced to 2 or less. Similarly, shoulder pain was more prevalent and intense in Group A across all four days, with Day 0 showing higher frequencies of VAS scores above 4. This aligns with the hypothesis that drain placement may exacerbate discomfort due to local irritation or tension.

Postoperative findings showed that surgical site infection (SSI) occurred in 3 cases (2.1%) in Group A and only 1 case (0.7%) in Group B. Fever was more common in the drainage group (12.3% vs 4.8%), further supporting concerns that drain placement may predispose patients to low-grade inflammation or infection. Nausea and vomiting were slightly more frequent in Group A, reinforcing earlier reports in literature that drains might stimulate vagal responses or increase discomfort.

Regarding hemorrhage, 3 cases were noted in Group A while none occurred in Group B. This difference, though small, could be attributed to minor bleeding from drain sites or surgical handling associated with drain placement. The absence of hemorrhage in the non-drain group suggests that omitting drains does not necessarily increase bleeding risks postoperatively. These findings align with current evidence discouraging the routine use of drains in uncomplicated laparoscopic cholecystectomy.

In conclusion, the study demonstrates that routine drain placement in laparoscopic cholecystectomy may not offer substantial benefits and may instead be associated with increased operative time, longer hospital stay, and higher incidence of postoperative discomfort and complications. Thus, a selective approach to drain use, guided by intraoperative findings and individual patient risk factors, appears to be more appropriate in modern surgical practice.

Conclusion

- Group A participants were significantly older and had a lower BMI compared to Group B, with both differences being statistically significant.
- There was no statistically significant difference in gender distribution between the two groups.
- Abdominal pain, fever, nausea, and vomiting were significantly more prevalent in Group A than in Group B, indicating a more symptomatic presentation.
- Murphy's sign was more commonly positive in Group A (11%) than Group B (2.7%), while the occurrence of a palpable lump was similar between groups.
- Group A showed higher mean values in TLC, S. Bilirubin, ALP, and RBS, while serum creatinine and INR were comparable across both groups.
- Positivity for viral markers (Hepatitis B, C, and HIV) was slightly higher in Group B, though overall prevalence was low.
- All patients underwent USG, while MRCP was performed more often in Group A.
- Drains were placed and removed in Group A only, typically between Day 2 and Day 4; no drains were placed in Group B.
- Group A had significantly longer operating times and slightly longer hospital stays compared to Group B.
- On Day 0, abdominal pain was more severe in Group A; Group B had more patients reporting moderate pain (VAS 5).
- By Day 1 and Day 2, Group B patients reported significantly lower pain scores, whereas Group A still showed higher VAS scores.
- By Day 3, most of Group B reported mild pain (VAS 2 or less), while Group A still had moderate pain scores (mostly VAS 3).
- Shoulder pain on Day 0 and Day 1 was more severe and frequent in Group A; Group B had more patients with no or mild pain.
- On Day 2 and Day 3, shoulder pain further subsided in both groups, but pain resolution was more complete in Group B.
- Postoperative complications such as SSI, fever, nausea, vomiting, and hemorrhage were more frequently observed in Group A than in Group B.

Limitations:

- The study was conducted at a single center, which may limit the generalizability of the findings to other populations or clinical settings.
- The sample size, though adequate for initial observations, may not be sufficient to detect rare postoperative complications with statistical power.
- Randomization was done, but the method of randomization and allocation concealment was not specified, which could introduce selection bias.
- The follow-up period was limited to only 3 postoperative days, potentially missing complications that could arise later.
- The study did not account for surgeon variability or experience, which could influence operative time and complication rates.
- Pain assessment using the Visual Analogue Scale is subjective and may vary based on individual pain thresholds and psychological factors.
- The observational study design limits the ability to establish causal relationships between drain use and postoperative outcomes.
- Certain exclusion criteria, such as conversion to open surgery or intraoperative complications, may limit applicability to more complex or emergent cases.
- Data on analgesic use, which could affect pain perception and reporting, was not documented or standardized across groups.
- The absence of long-term outcomes such as delayed infections, readmission rates, or overall recovery limits the comprehensiveness of the assessment.

BIBLIOGRAPHY

1) Shehadi WH. The biliary system through the ages. Int Surg 1979; 64:63.

2) Thudicum JLW. Part 1: historical introduction. In: Robinson JO, ed. Silvergirl‟s surgery: biliary tract. Austin, Texas: Silvergirl, 1985:4-13.

3) Sparkman RS, Bobes Centennial. The first cholecystectomy surgery 1967; 61:965.

4) Livingston E, Rege R. A nationwide study of conversion from laparoscopic to open cholecystectomy. Am J Surg 2004;188:205-11.

5) Alponat A, Kum C, Koh B, Rajnakova A, Goh P. Predictive factors for conversion of laparoscopic cholecystectomy. World J Surg 1997;21:629-33.

6) Fried G, Barkun J, Sigman H, Joseph L, Clas D, Garzon J,et al. Factors determining conversion to laparotomy in patients undergoing laparoscopic cholecystectomy. Am J Surg 1994;167:35-9.

7) Coccolini F, Catena F, Pisano M, et al. Open versus laparoscopic cholecystectomy in acute cholecystitis. Systematic review and meta-analysis [published correction appears in Int J Surg. 2015 Dec;24(Pt A):107]. Int J Surg. 2015;18:196-204. doi:10.1016/j.ijsu.2015.04.083

8) Thiebe U, Eggert A. Drainage after laparoscopic cholecystectomy. Minimal Invasive Chirurgie 1994;3:90-92.

9) Tzovaras G, Liakou P, Fafoulakis F, Baloyiannis I, Zacharoulis D, Hatzitheofilou C. Is there a role for drain use in elective laparoscopic cholecystectomy? A controlled randomized trial. Am J Surg 2009;197(6):759-63

10) Morozowicz A, Rucinski P, Polkowski W. Routine drainage of the subhepatic area after laparoscopic cholecystectomy. Prospective, controlled study with random patient selection. Polski Przeglad Chirurgiczny 2006;78(5):597-609.

11) Soper NJ, Stockmann PT, Dunnegan DL, Ashley SW. Laparoscopic cholecystectomy. The new 'gold standard'? Arch Surg. 1992 Aug;127(8):917-21; discussion 921-3. doi: 10.1001/archsurg.1992.01420080051008. PMID: 1386505.

12) Uchiyama K, Tani M, Kawai M, Terasawa H, Hama T, Yamaue H. Clinical significance of drainage tube insertion in laparoscopic cholecystectomy: A

prospective randomized controlled trial. J Hepatobiliary Pancreat Surg 2007;14(6): 551-56. 6.

13) Tzovaras G, Liakou P, Fafoulakis F, Baloyiannis I, Zacharoulis D, Hatzitheofilou C. Is there a role for drain use in elective laparoscopic cholecystectomy? A controlled randomized trial. Am J Surg 2009;197(6):759-63

14) Nagpal A, Goyal S, Abbey L, Singh A. Drainage in Cholecystectomy: Required or Not? A Comparative Randomized Study in Northern Indian Subjects. World J Lap Surg 2012;5(2):63-66.

15) Dharamdev D, Mascarenhas RM, Bhandary A.Comparative study of laparoscopic cholecystectomy with and without drains.Int Surg J2021;8:2633-6.

16) Gastrointestinal and liver disease, Sleisenger and Ford Trams, 7th ed, Pg 1091.

17) Halpert B, Carl Langenbuch. Master surgeon of the biliary system. Arch Surg 1932; 178.

18) Kuldip Singh, Ashish Ohri. Journal of minimal access. Surgery 2005 June; 1:59-61.

19) Filipi CJ, Fitzgibbons RJ, Salerno GM. Historical review: Diagnostic laparoscopy to laparoscopic cholecystectomy and beyond. In: Zucker KA (ed), Surgical laparoscopy. St. Louis MO. Quality Medical 1991; 3-21.

20) Litynski GS. Erich Muhe and the rejection of laparoscopic cholecystectomy (1985): a surgeon ahead of his time. JSLS, 1998 Oct-Dee; 2(4):341-6.

21) Tehemton E. Udwadia. Journal of minimal access. Surgery 2005 June; 1:51-52.

22) James Toouli. Surgery of the biliary tract. Churchill Livingstone 1993: Pg 135.

23) Richard L, Drake, Wayne Vogl, Adam W.M. Mitchell, Grays Anatomy for students, Churchill Livingstone, 2005; Pg 287.

24) Pitt HA, Gadacz TR. Biliary system. In, Shackelford‟ s Surgery of the Alimentary Tract V. Saunders Publishers. 2007;2:1444-9.

25) Sheila Sherlock, James Dooley. Diseases of the liver and biliary system, 9th ed, Blackwell Scientific Publications, 1991, Pg 63.

26) Gag Decker, du Plessis DJ, Lee Mcgregor's synopsis of surgical anatomy, 12th ed, Varghese Publishing house, 1999; Pg 89.

27) Courtney M. Townsend, Daniel Beauchamp R, Mark Evers B, Kenneth L, Mattox. Sabiston Textbook of Surgery, Elsevier, 17th ed, 2000; Pg. 1598-1600.

28) Chummy S. Sinnatamby. Last Anatomy, Regional and Applied, 10th ed, Churchill Livingstone, 2000; Pg 145.

29) Sanjay Nagral. Anatomy relevant to cholecystectomy. Journal of minimal access surgery, June 2005; 1:55-56.

30) Margret Oddsdottir, Thai Pham and John Hunter.Gallbladder and the Extrahepatic Biliary System. In, Schwartz‟s Principles of Surgery, McGraw Hill 2010; Ch 32; pg 1137-39.

31) Gamal Mostafa, Cathey Lamont, Frederick L. Greene. Review of Surgery : Basic Science and Clinical Topics for ABSITE. Springer; Ch 113,Pg 263.

32) C.Palanivelu, Art of Laparoscopic Surgery- Textbook and Atlas, Jaypee Publishers, Vol. 1, Chapter 36, pg 556.

33) Donovan JM, Carey MC. Physical-chemical basis of gallstone formation, Gastroenterol Clin North Am 199 1;20:47-66.

34) Wang D and Afdhal N.Gallstone disease,in Sleisenger and fordtran‟s Gastrointestinal Surgery,9th Edition, Saunders Elsevier,Philadelphia. Pp.1106-08.

35) Ravi S.Chari and Shimul A.Shah. Biliary system. In, Townsend (ed). Sabiston Textbook of Surgery Volume 2, 18th edition, South Asia edition. Philadelphia,Saunders Publishers, 2009;1558-62.

36) Ahrendt SA : Biliary tract Surgery. Curr Gastroenterol Rep 1: 107, 1999.

37) Lee HJ,Choi BI,Han JK et al: Three dimensional ultrasonography using minimum transparent mode in obstructive biliary diseases: Early experience. J Ultrasound Med 21:443, 2002.

38) Shlaer WJ, Leopold GR, Scheible FW. Sonography of the thickened gallbladder wall: a nonspecific finding. AJR Am J Roentgenol 1981; 136:337-339.

39) Chan Y-L, Chan ACW Lam WWM, et al. Choledocholithiasis: comparison of MR cholangiography and endoscopic retrograde cholangiography. Radiology 1996;200:85-9.

40) Margret Oddsdottir, Thai Pham and John Hunter.Gallbladder and the Extrahepatic Biliary System. In, Schwartz‟s Principles of Surgery, McGraw Hill 2010; Ch 32; pg 1141.

41) Marton KI, Doubilet P. How to image the gallbladder in suspected cholecystitis. Ann Intern Med 1988; 109:722- 727.

42) Wang D and Afdhal N.Gallstone disease,in Sleisenger and fordtran‟s Gastrointestinal Surgery,9th Edition,Saunders Elsevier,Philadelphia. Pp.1106-1119

43) Kirk RM. General surgical operations, 4th ed, Churchill Livingstone, 2000; Pg 397-400.

44) Richard DC Frazee, John W Roberts , Gyman C Okeson, Richard Symonds et al. Open versus laparoscopic cholecystectomy: A comparison of postoperative pulmonary function. Ann Surg 1991 June; 651-653.

45) Michael J. Zinner, Seymour L. Schwartz, Harold Ellis. Maingot‟s abdominal operations, 10th ed, Appleton and Lange 1997; Pg 1732-1735.117

46) Sir. Peter J. Morris, William C. Wood. Oxford textbook of surgery, 2nd ed, Oxford University Press 2000; Pg 1682.

47) Das S. A concise textbook of surgery, 2nd ed, S. Das Publications, 1999; Pg 907.

48) Ravimohan SM, Lileswar Kaman, Ravi Jindal, Rajinder Singh, Jindal S.K.Postoperative pulmonary function in laparoscopic versus open cholecystectomy: A prospective, comparative study, I J Gastroenterol 2005; 24:6-8.

49) Kevin Conlon. Bailey and Love Short Practice of Surgery, 25th ed, Arnold International 2000; Pg. 1124.

50) Majeed AW, Troy G, Nicholl JP, Smythe A, Reed MWR, Stoddard LJ et al. Randomized prospective single blind comparison of laparoscopic versus small incision cholecystectomy. Lancet 1996 April 13; 847: Pg 989-991.

51) Palanivelu C. Laparoscopic Cholecystectomy. In: Palanivelu C (ed). CIGES Atlas of Laparoscopic Surgery. 2nd edition. New Delhi: Jaypee Brothers Medical Publishers Pvt. Ltd., 2003 :39-43.

52) Palanivelu C. Laparoscopic cholecystectomy. In: Palanivelu C (ed). Textbook of Surgical Laparoscopy. Coimbatore: Gem Digestive Diseases Foundation, 2002: 121-138.

53) Ara Darzi, Mark A. Tolamine, David C. Dunn. Atlas of laparoscopic surgical techniques, W. B. Saunders Company 1997; Pg 64.

54) Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. JAm Coil Surg 1995; 180:101-125.118.

55) Agarwal S, Gupta A, Sharma R, et al. The impact of drains on seroma formation following laparoscopic cholecystectomy in cases with significant gallbladder bed dissection. *Indian Journal of Surgery*. 2010; 72(3): 171-175.

56) Rathi M, Kapoor R, Yadav K, et al. Effect of subhepatic drains on postoperative seroma formation and need for further interventions. *Journal of Gastrointestinal Surgery*. 2012; 16(5): 1040-1044.

57) Gupta R, Chawla V, Singh P, et al. The use of drains in laparoscopic cholecystectomy for acute cholecystitis: Impact on postoperative infection rates and bile leakage detection. *World Journal of Surgery*. 2015; 39(3): 589-595.

58) Surg K, Rao P, Kumar A, et al. Selective drainage in complicated laparoscopic cholecystectomy: Effect on postoperative outcomes and reoperation rates. *Journal of Minimally Invasive Surgery*. 2017; 22(4): 344-349.

59) Arslan R, Karahan O, Turan M, et al. The effect of drain localization on postoperative pain in laparoscopic cholecystectomy: a prospective randomized study. *Journal of Gastrointestinal Surgery*. 2012;16(7): 1373-1379.

60) Sharma S, Mittal S. A prospective randomized study on routine subhepatic abdominal

drainage following uncomplicated laparoscopic cholecystectomy. *Indian Journal of Surgery*. 2016;78(3): 195-200.

61) Yang J, Liu H, Zhang L, et al. A systematic review and meta-analysis protocol comparing laparoscopic cholecystectomy with and without abdominal drainage in patients with non-complicated benign gallbladder disease. *Cochrane Database of Systematic Reviews*. 2020;12: CD013157.

62) Akbar A, Khan I, Siddique M, et al. Outcomes of laparoscopic cholecystectomy with and without drain placement at Ayub Teaching Hospital. *Journal of Postgraduate Medical Institute*. 2022;36(2): 89-94.

63) Cochrane Review. Routine drainage versus no drainage following laparoscopic cholecystectomy: A meta-analysis of randomized controlled trials. *Cochrane Database of Systematic Reviews*. 2016; 4: CD008279.

64) Singh P, Verma S, Sharma D, et al. A systematic review on the role of selective versus routine drainage in laparoscopic cholecystectomy: Special considerations for difficult dissections and intraoperative bile spillage. *Journal of Gastrointestinal Surgery*. 2020; 24(6): 1334-1340.

65) Nayak SR, Sharma S, Mishra P, et al. Comparison of postoperative pain in laparoscopic cholecystectomy with and without drain placement: A randomized controlled trial. *J Minim Access Surg*. 2019;15(4):281-286. doi:10.4103/jmas.JMAS_185_19.

ANNEXURES

SANTOSH MEDICAL COLLEGE & HOSPITAL

Details of Patient Information Sheet
Human Subject Research Proposal

Subject ID Number:

Name of Researcher: Dr. Garima Rahul Mishra

Department: Department of General Surgery

Title of Project: "LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT DRAINAGE: A HOSPITAL BASED OBSERVATIONAL STUDY"

Description of Human Subjects Safeguards and Rights:

A general biodata of the patients regarding their name, age, sex, occupation, religion, socio-economic status and address will be collected.

Methodology to be used:

A detailed history of all patients are taken and a thorough clinical examination is done. All patients are analyzed on various aspects such as age, sex distribution, risk factors, mode of presentation, and laboratory investigations, type of surgery, and intra operative findings. Routine investigations will be done and patients will get admitted for Laparoscopic Cholecystectomy, the intra operative findings and postoperative findings also will be assessed.

The analyzed data will be compared with other series in literature and discussed. A master chart dealing with all aspects will be designed and presented. A proforma will be used for the study purpose.

There is no risk of psychological or physical harm to the patients directly related to the nature or methodology of the study.

Subjects are free to choose to leave the study at any point and are free to choose to stop sharing information as a part of the study, at which point, their participation in the study will be terminated and their data will not be used. Subjects will receive their collected study information.

CASE PROFORMA

S. No.:

Date:

Name:

BMI:

MRD No: Occupation:

Address:

Socio-economic status:

Final Diagnosis:

CHIEF COMPLAINTS:

HISTORY:
Pain:

Duration:

Location:

Character:

Radiation:

Aggravating factor /Relieving factor:

Fever:

Nausea:

Vomiting:

Dyspepsia:

Any other complaints:

PAST HISTORY:

Past history of recurrent abdominal pain:

EXAMINATION:

General physical examination:

Vitals:

Pulse

Blood pressure

Temperature

Respiratory rate

Pallor: Icterus: Clubbing:

Cyanosis: Oedema: Lymph Nodes:

Systemic examination:

Central Nervous System:

Cardiovascular System:

Respiratory System:

Abdomen Examination:

Inspection:

Palpation:

Murphy's sign:

Palpable Gallbladder:

Percussion:

Auscultation:

LAB INVESTIGATIONS:

1. Complete blood counts:

   Hb- TLC- Platelets-

   DLC- N L M B

2. Blood sugar (Random)-

3. Viral Markers:

HBsAg- HCV-

HIV 1&2-

4. Liver Function Test:

   S. Bilirubin Total - S. Bilirubin direct-

   S.G.O.T. - S.G.P.T.-

S. Alkaline Phosphatase-

5. Kidney Function Test:

Serum Creatinine-

6. P.T.- I.N.R-

RADIOLOGICAL INVESTIGATIONS:

1. USG Whole Abdomen (Ultrasound):

Gallbladder wall thickness-

Gallbladder wall edema-

Number and size of calculous-

Fluid in Morrison's pouch-

Impacted stone in hartmann's pouch-

CBD- Diameter:

2. MRCP (Magnetic Resonance Cholangiopancreatography):

SANTOSH MEDICAL COLLEGE AND HOSPITAL (GHAZIABAD)

INFORMED CONSENT

I_____Son/Daughter/Wife of _____ _____ resident of_____ _____hereby declare that I give my full, free and voluntary informed consent for participation in the study - **"LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT DRAINAGE: A HOSPITAL BASED OBSERVATIONAL STUDY"**. Dr. Garima Rahul Mishra has informed me to my full satisfaction, in the language I understand, about the purpose, nature of study and various laboratory investigations and procedures required for the study to be carried out. I have been informed about the duration of the study and instructions to be followed during the study period. I have received the information sheet on the above study and have read and/or understood the written information. I have been given the chance to discuss the study and ask questions. I give full consent for being enrolled in the above study and understand that my participation is voluntary. I reserve my rights to withdraw from this study, whenever I wish without prejudice of my right to undergo further treatment at Santosh Medical College and Hospital, Ghaziabad U.P. I understand that the information collected about me from participation in this research and sections of any of my medical notes may be looked at by responsible persons (ethics committee members/regulatory authorities). I give permission to these individuals to have access to those records. I understand I will receive a copy of the patient information sheet and the informed consent form.

Patient's/Patient's relative's signature or thumb impression Name:

Subject ID No. for Study:

Date:

We have witnessed that the patient signed the above form in the presence of his free will after fully understanding its content.

Signature of Witness

Name:

Signature of Principal Investigator
Name: Dr. Garima Rahul Mishra
Designation: PG Resident
Department of General Surgery
Contact No.- +919820165502

संतोष मेडिकल कॉलेज एवं अस्पताल (गाजियाबाद)

सहमति पत्र (सूचित)

मैं _____ बेटा / बेटी /पत्नी_____

निवासी _____ घोषणा करता हूं कि मैं

डॉ ._____, ने मुझे मेरी भाषा में अपने अध्ययन "**LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT DRAINAGE: A HOSPITAL BASED OBSERVATIONAL STUDY**"

अध्ययन के उद्देश्य के बारे में, और अध्ययन के दौरान अपनाई जाने वाली विभिन्न प्रयोगशाला जांच के बारे में सूचित कर दिया है। मुझे अध्ययनकी अवधि और उसके दौरान अपनाए जाने वाले निर्देश भी मेरी भाषा मे समझा दिए गए हैं| मैं उपरोक्त अध्ययन में बिना किसी दबाव के दाखिला ले रहा हूं और पूर्ण सहमति दे रहा हूं | सन्तोष अस्पताल, गाजियाबाद में अपने आगे के उपचार पर बिना प्रतिकूल प्रभाव डाले इस अध्ययन से और प्रयोगशाला जांच की प्रकृति से मैं जब चाहूँ बाहर जाने के अपने अधिकार को सुरक्षित रख रहा हूं |

रोगी / रोगी के रिश्तेदार के हस्ताक्षर डॉक्टर के हस्ताक्षर

नाम

दिनांक:

मेरी उपस्थिति में मरीज ने पूरी तरह से डाकटर के बताए गए अध्ययन और निर्देशों को समझने के बादअपनी स्वतंत्र इच्छा से ऊपर के फार्म पर हस्ताक्षर किए हैं ।हस्ताक्षर नाम: डॉ गरिमा राहुल मिश्रा

नाम: डॉ गरिमा राहुल मिश्रा

पदनाम: पीजी

शल्यचिकित्सा विभाग

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Subject: Grant of Ethical Clearance for **Thesis Protocol** Topic **"LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT DRAINAGE : A HOSPITAL BASED OBSERVATIONAL STUDY",** submitted by **Dr. MISHRA GARIMA RAHUL,** MD/MS student of Batch 2022-2023, Department of **GENERAL SURGERY.**

*****

With reference to his/her request for grant of Ethical Clearance for the Thesis Protocol entitled **"LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT DRAINAGE : A HOSPITAL BASED OBSERVATIONAL STUDY", Dr. MISHRA GARIMA RAHUL** is informed that the **Thesis Protocol** submitted by him/her was considered by the **Screening Committee** of the Santosh Medical College & Hospital in its meetings held on 17.07.2023 to 28.07.2023. The recommendations of the **Screening Committee** were considered in detail by the **Institutional Ethics Committee** in its meeting held on **23.09.2023** and the same was **approved** by the **Ethics Committee.**.

He /She is informed accordingly for further necessary action.

[Dr. NARESH SHARMA]
REGISTRAR

Dr. MISHRA GARIMA RAHUL
MD/MS student of batch 2022-2023
Department of GENERAL SURGERY
Email: garimarahulmishra@gmail.com

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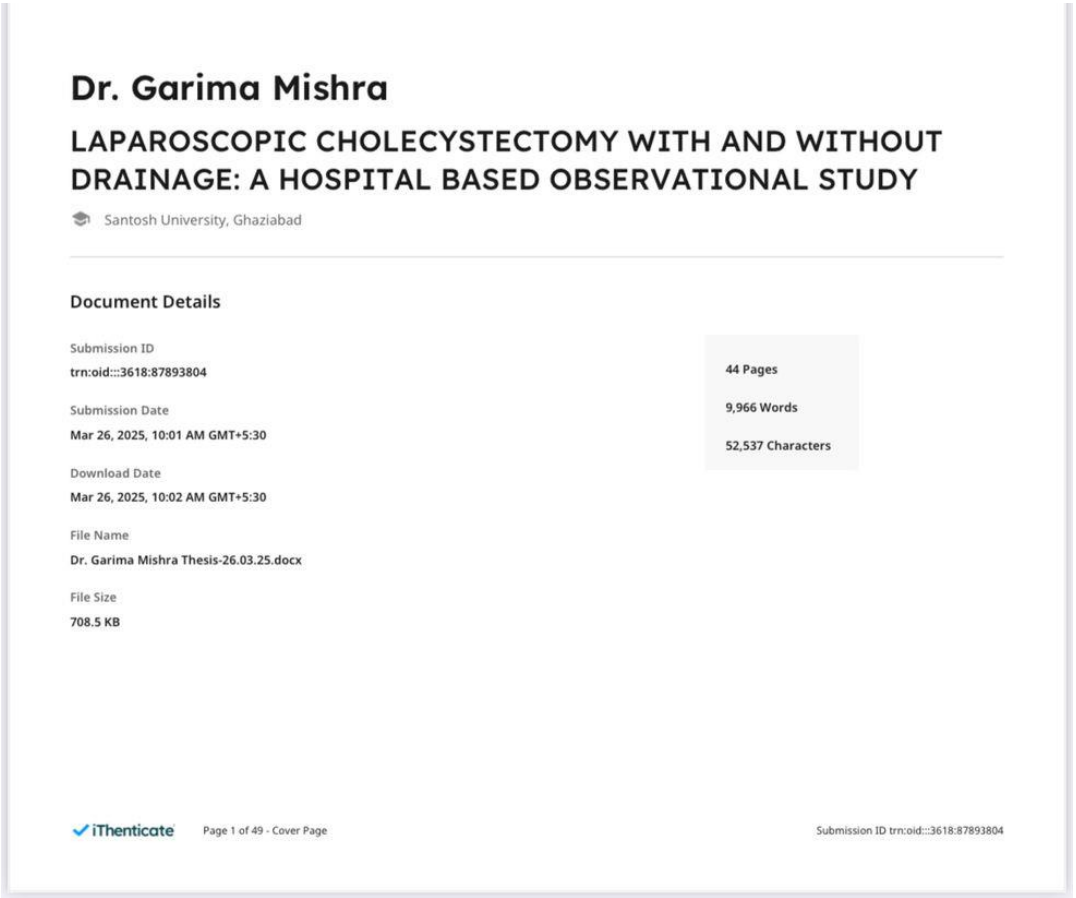

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LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT DRAINAGE: A HOSPITAL BASED OBSERVATIONAL STUDY

Santosh University, Ghaziabad

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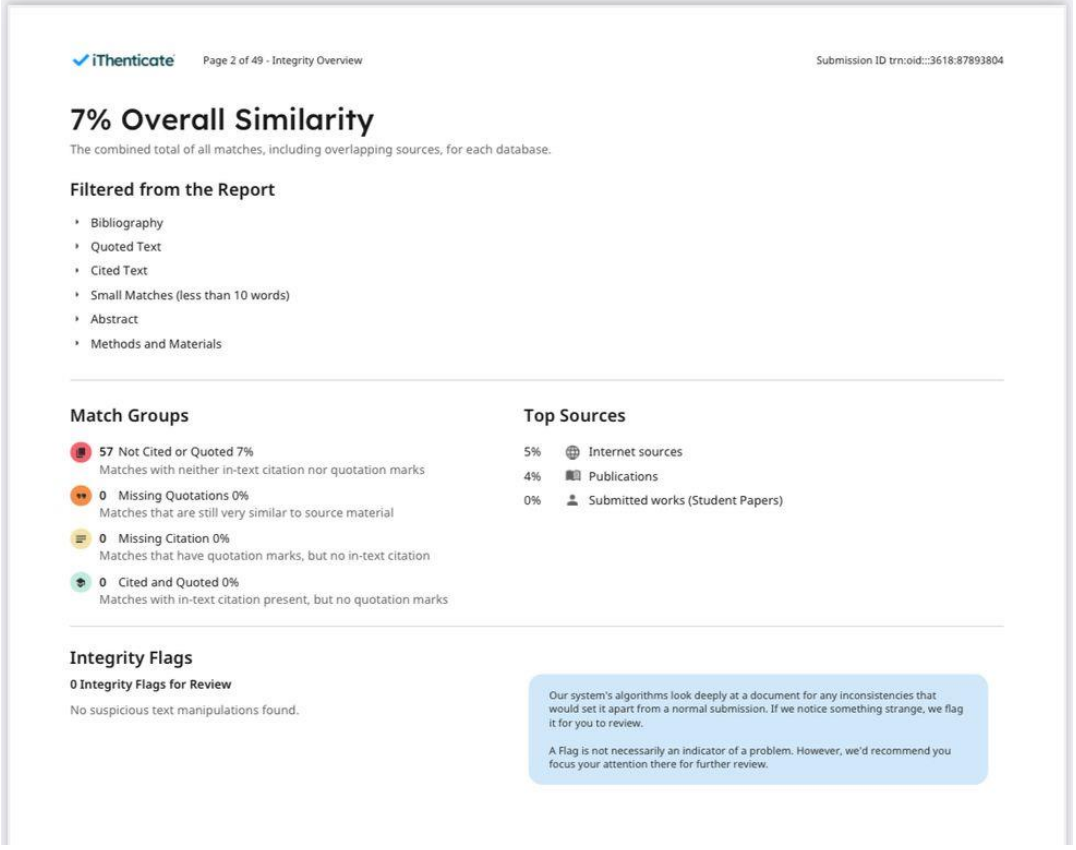

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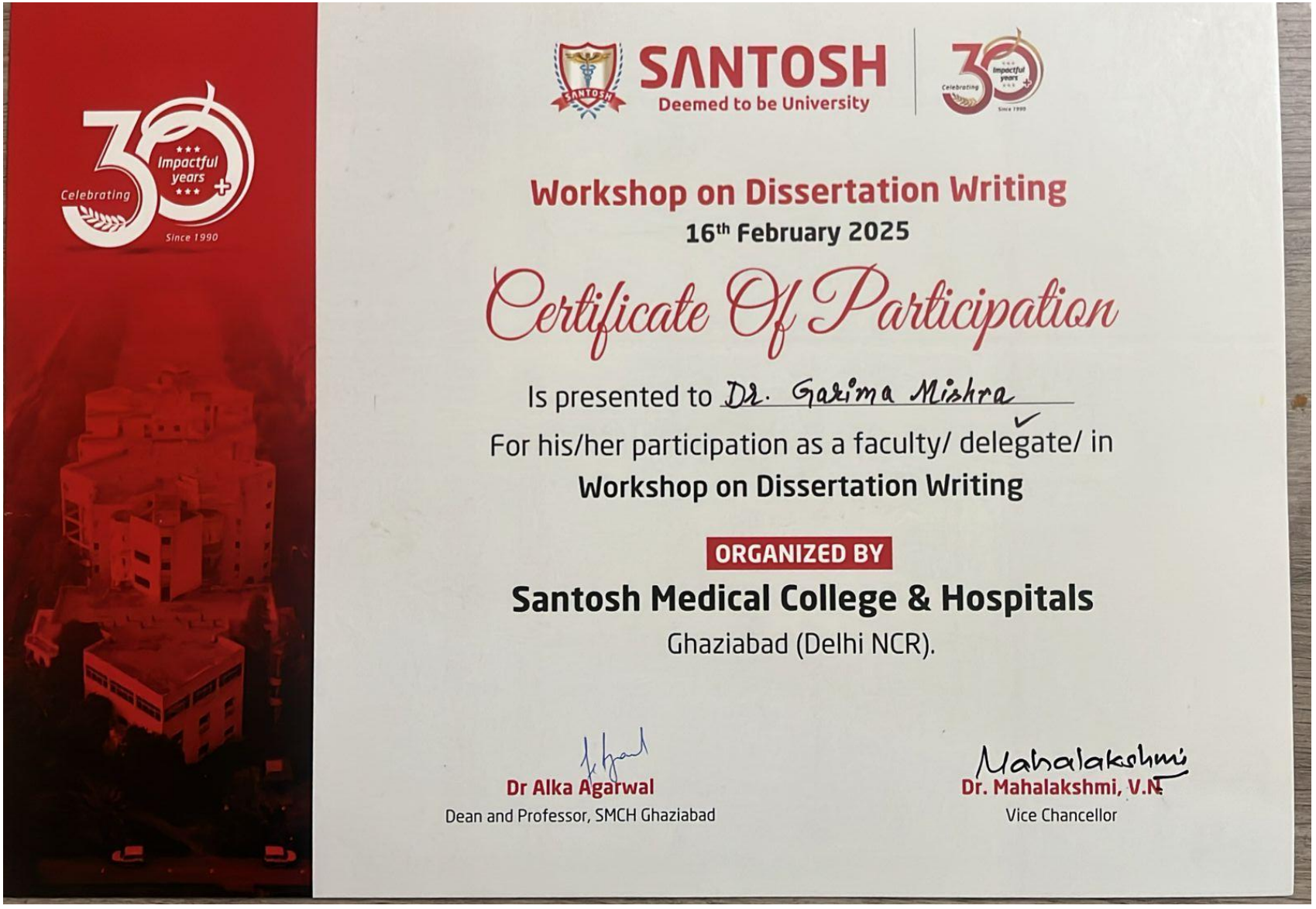

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